IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of		Confirmation No.: 6092
	Ian CLARKE, et al.	Date: April 15, 2010
Serial No.:	10/533,842	Group Art Unit: 3761
Filing Date:	May 4, 2005	Examiner: Philip R. WIEST
For:	LIQUID DISPENSER	

VIA EFS-WEB
Mail Stop Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Sir:

This Brief is submitted in support of Applicants' appeal from the Examiner's rejection of this application dated August 18, 2009.

I. REAL PARTY IN INTEREST

The real party in interest in the above-identified application is: Keystone Product Developments Pty Ltd, a corporation organized under the laws of Australia, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

The applicants, assignee, and the undersigned attorneys are not aware of any related appeals and interferences.

III. STATUS OF CLAIMS

Claims 1, 2, 4, 7, 9-11, 15 and 19-21 are pending and rejected and on appeal herein.

Claims 3, 5-6, 8, 12-14 and 16-18 are canceled.

All pending claims have been previously presented. Claims 3, 7, 9-11, 14-15 were amended and Claims 5-6, 8, 12-13 and 16-18 were canceled in the Preliminary Amendment of May 4, 2005. Further, Claim 1 was amended on January 30, 2007, August 10, 2007, February 19, 2008, August 27, 2008 and July 30, 2009. Claim 2 was amended on January 30, 2007, August 10, 2007, February 19, 2008 and August 27, 2008. Claim 3 was amended on January 30, 2007 and then canceled on August 10, 2007. Claim 4 was amended on January 30, 2007 and August 10, 2007. Claim 14 was canceled on January 30, 2007. Claims 7 and 15 were amended and Claim 19 was added as new on January 30, 2007. Claims 11, 15 and 19 were further amended on August 27, 2008. Claim 20 was added on August 10, 2007. Finally, Claim 21 was added on July 30, 2009.

IV. STATUS OF AMENDMENTS

All amendments have been entered. The sixth Office Action on the merits was issued on August 18, 2009. A Notice of Appeal was filed on February 17, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

There are many situations where it is desirable to be able to provide a controlled low flow rate delivery of a liquid from a compact, portable and reliable device. In particular, there are many medical situations in which it is desirable to supply liquids such as intravenous drip fluids for patients in a reliable and easily regulated device which at the same time is compact and portable so that it is convenient for the patient to use.

In the past, low flow rate dispensing devices, and in particular intravenous drip supply devices, have been provided in a number of different formats including the conventional gravity feed bag which is typically hung from a support rack located above the patient. Such devices are

cumbersome for the patient to use, requiring the feeding of a tube from a fixed and elevated situation to the point of dispensing on the patient and furthermore they are not readily portable.

Broadly stated, the apparatus defined by Claims 1, 2, 4, 7, 9-11, 15 and 19-21 are directed to overcome the above problem.

Independent claim 1, directed to the apparatus according to the invention, recites:

Claim Feature	**Support in Specification**
An apparatus for controlled rate dispensing of a liquid contained in a flexible bag, said apparatus including:	Page 2, lines 7 - 8; and Fig. 4 (*see, flexible bag 9)*
a chamber configured to contain the flexible bag, the flexible bag having exterior walls and having an outlet conduit for the liquid;	Page 5, lines 9 and 14-20; and Figs. 1 and 4 (*see, chamber 1, flexible bag 9, outlet conduit 12*)
a source of gas arranged to provide gas to apply pressure to at least part of the exterior walls of the flexible bag in the chamber; and	Page 5, lines 23-25; and Figs. 1 and 4 (*see, pressure vessel 15*)
a pressure regulator positioned between the source of gas and the flexible bag, the pressure regulator being configured to continuously self-regulate a pressure of the gas supplied from the source of gas to continuously maintain the pressure of the supplied gas at a constant and predetermined level and so as to continuously maintain the pressure applied to the exterior walls of the bag at the constant and predetermined level throughout a duration of dispensing of the liquid,	Page 6, lines 1-3 and 16-24; and Figs. 1 and 4 (*see, pressure regulator 16*)
whereby the pressure applied to the exterior walls causes liquid to be dispensed from the flexible bag through the outlet conduit at a controlled rate.	Page 6, lines 16-24; page 7, lines 1-4

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over Patent No. CA 2,083,555 to Laing ("Laing") in view of Patent No. GB 2,165,312 to Keime ("Keime").

B. Whether Claim 21 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Laing in view of Keime and further in view of U.S. Patent No. 4,666,430 to Brown ("Brown")

VII. ARGUMENT

A. Rejection of Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 under 35 U.S.C. §103(a)

1. Claim 1 is not obvious under 35 U.S.C. §103(a)

Claim 1 recites a pressure regulator positioned between the source of gas and the flexible bag. As recited in Claim1, and disclosed in the original specification (see, page 6, lines 16-19), the pressure regulator self-regulates the pressure of the gas supplied from the source of gas such that this pressure of the supplied gas is maintained at a constant and predetermined level throughout the duration of dispensing the liquid. In other words, the pressure regulator itself (i.e., without using any additional mechanism) maintains the constant and predetermined pressure of the supplied gas throughout dispensing of the liquid. Further, as a result of maintaining the pressure of the supplied gas at the constant and predetermined level, the flow rate of the liquid from the flexible bag is continuously constant because the pressure applied to the exterior walls of the flexible bag is also maintained at the constant and predetermined level. As evidenced by the Dastoor Declaration, this advantage is not realized by the cited references and cannot be achieved by the devices disclosed therein.

Laing discloses a flexible bag 40 located inside a rigid housing 20 and a pressure pump 58 connected to an air bag 30 inside the housing 20 through a line 35. As air is supplied to the air bag inside the housing, the air bag expands and applies pressure to the flexible bag 40 causing it to dispense fluid. As the fluid is dispensed from the bag 40 through an outlet line 45, the pressure of the dispensed fluid is monitored using an isolation device 60 connected to both the outlet line 45 and

the pump 58. Laing teaches that when the fluid pressure in the outlet line 45 falls below a set level, isolation device 60 communicates with the pump 58 causing the pump to pump more air, thus, increasing the air pressure inside the air bag 30 and increasing the pressure on the flexible bag 40. See, Laing, page12, line 25 - page 13, line 9 (emphasis added). Therefore, in Laing, the pressure of the air supplied from the pump is not continuously maintained at the constant and predetermined level, as required by Claim 1, and the pressure applied to the flexible bag is not continuously maintained at the constant and predetermined level, as also required by Claim 1. Instead, the on/off system of Laing keeps the pressure within a desired fluctuation range.

Further, as shown in the enclosed Dastoor Declaration, as a result of the pressure fluctuations in a prior art device constructed similarly to the device disclosed in Laing, such prior art device cannot achieve the accuracy results achieved by the device constructed in accordance with Claim 1. The flow variation of the prior art device is approximately 6.7%. The flow variation for the device of Claim1 is 0.8%. From a clinical perspective, a flow variation of 0.8% (for the device constructed in accordance with Claim 1) is significantly more accurate than the flow variation of 6.7% of the discussed prior art device. Moreover, while the prior art device discussed in the declaration can be made more accurate by adding several additional feedback loops, such device would become commercially and logistically impractical. Accordingly, the device constructed in accordance with Laing disclosure cannot be utilized in medical applications requiring high degree of precision (for which the device of the present Application is designed).

The Examiner argued in the Office Action that Laing "recognizes that constant flow is achieved by maintaining a constant pressure within the chamber." See, Office Action, page 3. However, according to Laing's drawings, the device starts operating with a full saline bag having a contact area of approximately 40% (estimating from the drawings) with the surrounding surfaces, and finishes operating with the area of contact being approximately 80% (as the bag empties). See, Laing, Figs. 1-3. Thus, using a standard Pressure = Force x Area formula, the gas regulation system of Laing approximately halves the pressure of the supplied gas (i.e., the "force" applied to the "area") throughout the infusion period to compensate for the increased contact surface area between the saline bag and the surrounding surfaces. Therefore, contrary to the recitations of Claim 1, Laing does not maintain the constant and predetermined pressure of the supplied gas throughout

dispensation of the liquid. Moreover, because of the discussed surface area changes, Laing cannot reliably adjust pressure by measuring the input pressure levels. Therefore, Laing has to have the pressure feedback from the liquid output to measure the output pressure to adjust the pressure on the bag. This additional structure is eliminated in the apparatus of Claim 1 by maintaining the predetermined pressure of the supplied gas throughout the infusion.

Keime cannot remedy the above deficiency of Laing because Keime discloses a portable device for use in a rapid infusion delivery environment, i.e., where a constant delivery rate is not clinically required. See, Keime, page 1, lines 7-10. Specifically, Keime discloses a manually operable pressure injector in which, after a needle is introduced into a patient, the operator changes the pressure applied to the flexible bag 2 by manually operating the flow regulator 23 adjusting the flow of gas into the casing 1 containing the flexible bag (Keime, page 2, lines 76-85). The operator continually consults the pressure gauge 17 on the face of casing 1, which indicates the pressure in the inner space of the casing and adjusts the pressure during dispensation of the fluid using the flow regulator 23 (Keime, page 2, lines 20-22 and 81-90). Thus, the Keime device constantly overshoots a predetermined pressure threshold and then allows the operator to manually adjust the pressure. Therefore, the pressure and the flow-rate of the liquid fluctuate throughout the delivery process. See, Dastoor Declaration, par. 18.

Further, contrary to the Examiner's arguments, a combination of the Laing pressure transfer system with Keime pressure regulator will not produce constant infusion. Instead, if the gas pressure (i.e., the force applied to the bag) is held constant, such combination will gradually increase an hourly output rate (to approximately double) of the fluid delivery during the infusion process, as the surface contact area between the saline bag and surrounding surfaces (as taught in Laing) increases during the process.

Accordingly, neither Keime nor Laing, alone or in combination, disclose or suggest a pressure regulator continuously maintaining the pressure of the supplied gas at the constant and predetermined level throughout dispensation of the fluid or a pressure regulator continuously maintaining the pressure applied to the flexible bag at the constant and predetermined level throughout dispensation of the fluid, as required by Claim 1.

Accordingly, even taken together in combination, Keime and Laing do not disclose or suggest the recitations of Claim 1.

2. Claim 7 is not obvious under 35 U.S.C. §103(a)

Claim 7 depends on the base Claim 1 and an interfering Claim 4. Accordingly, Claim 7 incorporates all limitations of Claim 1 discussed above and incorporates a limitation of Claim 4 of the inflatable bladder contacting at least part of the flexible bag. Additionally, Claim 7 recites that the inflatable bladder is an inflatable sock 24 wrapped around at least a part of the flexible bag 25. See, Application, par [0045], and Figs. 7-9.

Contrary to the Examiner's arguments, the above limitation of Claim 7 is not disclosed or even suggested in Laing. Instead, Laing discloses plates 22a and 23a applying pressure on the saline bag 40. See, Laing Figs. 3 and 5. These plates are neither inflatable nor do they wrap around the saline bag. Further, the air bag 30, which is inflatable does not wrap around the saline bag 40, and is not in contact with the saline bag, contrary to the recitations of Claims 4 and 7.

Thus, Applicants' dependent claim 7 is patentably distinct from Keime and Laing on its own merits, as well as for the reasons discussed with respect to Claim 1.

3. Claims 2, 4, 9-11, 15, 19 and 20 are not obvious under 35 U.S.C. §103(a)

Claims 2, 4, 9-11, 15, 19 and 20 depend directly or indirectly from the above discussed independent claim 1 and are, therefore, patentable for the same reasons, as well as because of the combination of features in those claims with the features set forth in the independent claim.

B. Rejection of claim 21 under 35 U.S.C. §103(a)

1. Claim 21 is not obvious under 35 U.S.C. §103(a)

Claim 21 depends directly from the above discussed independent claim 1 and is, therefore, patentable for the same reasons, as well as because of the combination of features in this claim with the features set forth in the independent claim.

VIII. CONCLUSION

Claim 1 and its dependent claims should be deemed allowable over the prior art of record.

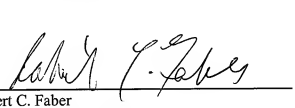
If this communication is filed after a time period has elapsed and no separate Petition is enclosed, the Commissioner of Patents and Trademarks is petitioned, under 37 C.F.R. §1.136(a), to extend the time for filing this Brief by the number of months which will avoid abandonment under 37 C.F.R. §1.135. The fee under 37 C.F.R. §1.17 should be charged to our Deposit Account No. 15-0700.

In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON April 15, 2010.

RCF/AV:dl

Respectfully submitted,



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CLAIMS APPENDIX

1. (Previously Presented) An apparatus for controlled rate dispensing of a liquid contained in a flexible bag, said apparatus including:

a chamber configured to contain the flexible bag, the flexible bag having exterior walls and having an outlet conduit for the liquid;

a source of gas arranged to provide gas to apply pressure to at least part of the exterior walls of the flexible bag in the chamber; and

a pressure regulator positioned between the source of gas and the flexible bag, the pressure regulator being configured to continuously self-regulate a pressure of the gas supplied from the source of gas to continuously maintain the pressure of the supplied gas at a constant and predetermined level and so as to continuously maintain the pressure applied to the exterior walls of the bag at the constant and predetermined level throughout a duration of dispensing of the liquid,

whereby the pressure applied to the exterior walls causes liquid to be dispensed from the flexible bag through the outlet conduit at a controlled rate.

2. (Previously Presented) The apparatus according to claim 1, wherein

the chamber is a substantially gas-tight chamber comprising a liquid outlet configured to receive the outlet conduit and operable to seal the outlet conduit to the chamber,

and

the source of gas is operable to supply the gas under pressure to the interior of the chamber applying pressure to the exterior walls of the flexible bag.

3. (Canceled)

4. (Previously Presented) The apparatus according to claim 1, further comprising an inflatable bladder, wherein the source of gas is connected to the inflatable bladder which is placed and operable such that, in use, the inflatable bladder is in contact with at least part of an exterior wall of the flexible bag.

5. – 6. (Canceled)

7. (Previously Presented) The apparatus according to claim 4, wherein the inflatable bladder comprises an inflatable sock positioned and operable to wrap around at least part of the flexible bag.

8. (Canceled)

9. (Previously Presented) The apparatus according to claim 1, wherein the source of gas comprises a pressure vessel of pre-compressed gas.

10. (Previously Presented) The apparatus according to claim 1, wherein the source of gas comprises a reservoir pressurised by a pump.

11. (Previously Presented) The apparatus according to claim 1, wherein the flexible bag is a medical supply bag of a type used to supply intravenous drip fluids for patients.

12. – 14. (Canceled)

15. (Previously Presented) The apparatus according to claim 9, wherein the chamber has a cuboidal configuration with a depth significantly less than a length or width of the chamber, and wherein the pressure vessel and the pressure regulator are located alongside the chamber in a common housing arranged such that the pressure vessel and the pressure regulator are contained within the depth of the housing.

16. – 18. (Canceled)

19. (Previously Presented) The apparatus according to claim 4, wherein the pressure regulator is operable to regulate a flow of gas from the source of gas into the inflatable bladder.

20. (Previously Presented) The apparatus according to claim 1, wherein the apparatus comprises a second chamber comprising the source of gas and the pressure regulator.

21. (Previously Presented) The apparatus according to claim 1, wherein the pressure regulator is a compression spring controlled piston device including at least one needle valve operable to regulate the pressure of the gas supplied from the source of gas.

EVIDENCE APPENDIX

EXHIBIT 1: Declaration of Paul Christopher Dastoor.

RELATED PROCEEDINGS APPENDIX

None.

EXHIBIT 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Ian CLARKE, et al.

Serial No.: 10/533,842

Filed: May 4, 2005

For: LIQUID DISPENSER

Confirmation No.: 6092

Group Art Unit: 3761

Examiner: Philip R. Wiest

VIA EFS-WEB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

Paul Christopher DASTOOR declares as follows:

1. I am one of the inventors of the subject matter that is disclosed and claimed in the above-identified patent application.

2. I submit this Declaration in response to the rejection of the claims in the present application on the basis of the assertion by the Patent Examiner in the Final Office Action dated November 5, 2008 (Office Action).

3. I have a Bachelor of Arts degree and a Master of Arts degree in Natural Sciences and a Doctor of Philosophy degree in Physics, all from the University of Cambridge, England.

4. I am currently a full Professor of Physics and Director of the Centre for Organic Electronics with The University of Newcastle. The University of Newcastle Research Associates Limited (now known as Newcastle Innovation Limited) is the commercialization arm of the University of Newcastle.

5. I have been engaged in developing liquid dispensers of the type claimed in the present patent application for the past ten years. In my role as a Professor of Physics I have been implementing the principles of fluid dynamics and fluid flow to the area of medical dispenser bags for more than ten years.

6. I have studied the current claims of the above-referenced patent application.

7. Claim 1 currently recites:

> An apparatus for controlled rate dispensing of a liquid contained in a flexible bag, said apparatus including:
>
> a chamber configured to contain the flexible bag, the flexible bag having exterior walls and having an outlet conduit for the liquid;
>
> a source of gas arranged to provide gas to apply pressure to at least part of the exterior walls of the flexible bag in the chamber; and
>
> a pressure regulator positioned between the source of gas and the flexible bag, the pressure regulator being configured to self-regulate a pressure of the gas supplied from the source of gas to maintain the pressure of the supplied gas at a constant and predetermined level and so as to maintain the pressure applied to the exterior walls of the bag at the constant and predetermined level throughout a duration of dispensing of the liquid, the pressure regulator being further configured to self-regulate the pressure of the supplied gas and the pressure applied to the exterior wall continuously throughout the duration of dispensing of the liquid,
>
> whereby the pressure applied to the exterior walls causes liquid to be dispensed from the flexible bag through the outlet conduit at a controlled rate.

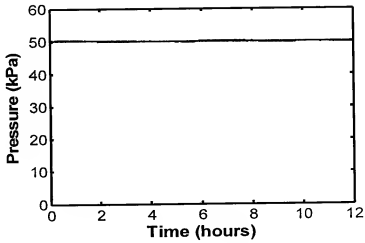
8. For a number of medical applications such as the delivery of highly toxic drugs for chemotherapy it is critical to have a constant pressure to a high degree of accuracy applied to the bag because this results in a constant and predetermined rate of flow which is critical for the dispensing of drugs in these applications.

9. The following data was obtained using a prototype liquid bag constructed in accordance with recitations of Claim 1.

Time (hours)	Pressure (kPa)
1.0	50.2342
2.0	50.0596
3.0	50.0283
4.0	49.9428
5.0	49.9452
6.0	49.9957
7.0	49.9668
8.0	49.9476
9.0	49.8428
10.0	49.8825
11.0	49.9464
12.0	49.8404

Although the data in this chart gives the pressure at 1 hour intervals, these numbers are representative of a much larger sample. In the actual test performed the pressure was taken every 2 seconds. This resulted in over 10,000 data points which were used to generate the graph shown in paragraph 10 below.

10. The data from the test referred to in paragraph 9 is shown graphically below where the pressure appears to be substantially constant.

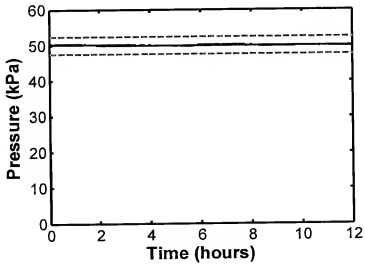


11. Accuracy data for the device constructed in accordance with recitations of Claim 1 correlates with the above pressure variation data and shows that an accuracy of better than 1% is achievable using the device of Claim 1.

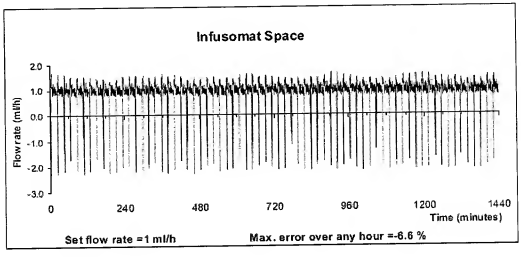
12. I have studied the cited prior art references: UK Patent Application No. GB 2165312 A to Keime ("Keime") and Canadian Patent Application No. CA 2083555 to Laing ("Laing").

13. Laing discloses an apparatus where the pressure applied to the bag fluctuates between two thresholds. Therefore, the pressure is not constant and does not result in a constant and predetermined rate of flow making the Laing apparatus unacceptable for use in an environment requiring delivery of precise dosage of medication at a constant and predetermined rate of flow.

14. The following graph was drawn from data obtained by comparing the apparatus constructed in accordance with the recitations of Claim 1 (solid line) with the typical thresholds (dashed lines) estimated from independently assessed data for a pump with an electronic control unit, of which Laing is a classic example. See, Centre for Evidence Based Purchasing, Report 06022, November 2006, NHS Purchasing and Supply Agency, UK, hereinafter "the Report." (attached hereto)



15. The actual flow rate/pressure fluctuations of the pump studied in the Report are shown in Figure 25 of the Report, reproduced for convenience below.



16. I have studied the above data and conclude that the apparatus of Claim 1 results in a substantially constant rate of flow of the medication compared with electronically controlled units such as Laing where the pressure fluctuates between the upper and lower thresholds shown above.

17. I have also studied the accuracy data for the electronically controlled unit such as Laing and compared it to the accuracy data for the device constructed under Claim 1. Specifically, as shown in the Report, long term accuracy results for the B. Braun Infusomat Space (i.e., the electronically controlled pump) range from –6.6% to +0.1%. See, Report, page 53. This is significantly worse than the above-mentioned accuracy results for the prototype constructed under Claim 1. This advantage is achieved by regulating the pressure supplied to the bag such that the pressure is supplied at the constant and predetermined level.

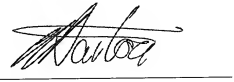
18. Keime discloses an infusion apparatus which constantly overshoots some predetermined pressure threshold and then allows the operator to manually adjust the pressure. Accordingly, the pressure, and consequently the rate of flow, fluctuates throughout the delivery process.

19. Keime involves a portable device for use in a rapid infusion delivery environment, e.g., "in case of road accident victims." See, Keime, page 1, lines 7-10 where a constant delivery rate is not clinically required. Therefore, Keime is not concerned with precision of delivery.

20. I further declare that all statements made herein are made of my own knowledge and are true except for those statements made on information and belief, which are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this declaration of this application and any United States patent issuing therefrom.

24th July 2009

Date



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EVALUATION

Report 06022

B. Braun Space volumetric and syringe pumps and Codan/Argus 708 volumetric pump

November 2006

Health and social care working together

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B. Braun Space volumetric and syringe pumps and Codan/Argus 708 volumetric pump

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Overall summary

This report is a technical evaluation of three pumps: two volumetric pumps using dedicated administration sets, both offering set-based anti free-flow protection, dose limiting software as an option, and a range of advanced features. The Codan/Argus volumetric (Codan/Argus 708) also offers bar coding as an option; the B. Braun volumetric (Space Infusomat) offers advanced networking and connectivity and a completely redesigned user interface.

The report also covers the sister pump to the B. Braun volumetric, the Space Perfusor syringe pump. This offers all standard features, and includes the redesigned user interface in common with the Infusomat. In addition, a number of other advanced features are offered, including automatic positioning of the drive carriage when loading the syringe.

Technical, usability and user assessments are presented. Manufacturer's data, product support and product specifications are listed, and previously unpublished protocols are presented in the appendix for usability testing.

All three pumps were found to have some features which scored poorly in the usability assessments. Technical evaluation revealed typical performance for volumetric and syringe pumps respectively with nothing outstandingly good or detrimental for any of the three pumps. Technical problems for all three pumps were identified during evaluation and are listed under "Faults during testing". Both Codan and B. Braun have put remedies in place for these faults, and retrospectively implemented them on all pumps in the field. No pumps purchased subsequent to the publication of this report should include these faults.

Codan Argus 708 summary

Brief description

The Codan Argus 708 is a volumetric infusion pump offering standard features as well as some specialised therapies including blood transfusions and parenteral nutrition.The pump is relatively light and compact (2 kg, 19 (w) x 16 (h) x 13 (d) cm) and can be used on a table top, or mounted using the integral pole clamp. A docking station (100 M or P) is offered, allowing pumps to share a single power cable. The docking station can also accommodate Codan Argus 600S syringe pumps. The Codan Argus 60 and 100 M-version docking stations enable communication between 3 or 5 pumps and facilitate configuration of multiple pumps, and the use of bar coding and dose limiting software. A central docking station can be supplied for connection to Patient Data Management Systems. P-versions of the docking stations are available without the data transfer capability.

The pump can be programmed for rate, volume to be infused (VTBI), and volume over time. Both pre-set and manual bolus deliveries are offered.

Comprehensive alarms are offered and a large dual red light on the pump forms a distinctive alert. The limited 7-segment display, however, restricts the usefulness of alarm messages, making understanding and rectifying alarms problematic at times. Occlusion alarm settings include special low pressure settings designed for neonatal applications. The usability problems encountered with the pump could preclude use of the pump for critical applications until remedied however.

Accessories for the pump include a drop detector, bar code reader and associated software, and a bottle holder.

Advantages

- Sets have an integral anti-free-flow clamp
- Distinctive visual alarm indicator
- Fast response to downstream occlusions
- Good short-term accuracy
- Effective upstream occlusion alarm (if optional drop detector used)
- Dose limiting software available
- Docking station available
- Not possible to close the door until the anti free-flow clamp is loaded
- Bar coding capabilities available
- Small, light, eyecatching design

Disadvantages

- Seven segment display is inadequate to give clear meaningful messages
- Highly configurable design may lead to confusion over basic functions
- Nearly instant switch off (as configured for evaluation)*
- Switching the pump off resets the displayed parameters to default values
- Pressing the STOP button activates KVO (as configured for evaluation)*
- Mode/alarm silence dual function key can cause confusion
- Instruction manual not entirely clear*
- Set change interval only 24 hours

*BIME Note: (see manufacturer's comments p.80)

Faults during testing

- It was found to be possible to misload the administration set (figure 1) and permit free flow that went undetected by the drop detector for a significant period whilst the pump was running - 450 ml of fluid free-flowed before alarm. A hardware solution to this problem has been demonstrated by the manufacturer and should be fitted on all pumps by the end of September 2006.
- Fault code F-52 was generated by the pump following an attempt to restart the infusion after reconnection to mains following the "battery empty" alarm, but before complete shut down due to the depleted battery. The alarm was cancelled by powering the pump off. On restarting, the pump operated normally and the fault did not recur.

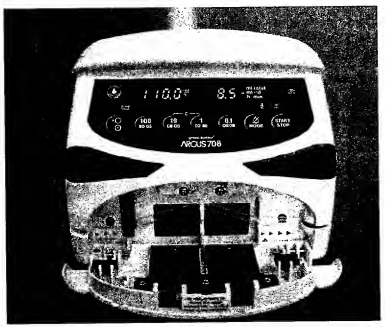


Figure 1. Misloaded set, giving rise to free flow without alarm.
Note: the door plate has now been modified to prevent the door being shut with set misloaded in this manner.

Main features

Power supply	230 +/-10% V AC, 50/60 Hz mains power; external 20 V/ 0.3A DC; internal rechargeable NiMH battery 12 V/ 1.5 Ah
Administration set	The pump was tested with the IVIP 708 B 86-Y administration sets
Flow rate range	0.1 to 999.9 ml/h in 0.1 ml/h steps
Pump mechanism	Peristaltic
Occlusion detection	75 – 750 mmHg (in 10 steps)/ 45 mmHg neonatology mode
Air detection	Single bubble detection 50 – 1000 µl (programmable), default 250 µl Bubble accumulation 100 – 2000 µl (50 µl steps) over 8-64 min (configurable)
Alarm and alert	Alarms: air in line, downstream occlusion, upstream occlusion, battery empty, door open, flow error (if drop detector in use), end of infusion, failed initial safety check, technical failure, stand-by pre-alarm: battery low staff alerting system: nurse call
Price (ex VAT)	£1750
Manufacturer	Codan Argus AG, CH-3627 Heimberg, Switzerland
CE marking	Yes
Notified body	0120, SGS United Kingdom, Limited
Certified to Standard?	ISO 9001: 2000; ISO 13485: 2000; EN 60601-1-1, EN 60601-1-4, EN 60601-2-24, EN 61000-3-2, EN 61000-3-3, EN 60601-1-2

Configuration

The pump offers the following functions that can be turned on or off in the configuration: IV set selection, priming the line using the pump, bolus delivery (automatic and manual), selectable occlusion alarm pressure limit, keypad lock, stand-by mode, input of medication name, timer alarm, stand-by reminder, patient transport mode, and neonatology mode. The patient transport mode allows the pump to run without triggering a drop alarm in the event that excess drops are detected. The drop alarm is still activated if no drops, or too many drops are detected within a certain time. Neonatology mode provides an option to set a lower occlusion alarm pressure limit. The available range of rate and volume to be infused are not changed in this mode.

In the pump supplied for the evaluation only the following functions were configured to be active: selectable occlusion alarm level, neonatology mode (activated only after the beginning of infusion), input of medication name, and checking the remaining battery capacity. The other functions were configured to be inactive.

In addition to the configurable functions, many other parameters are controlled by the configuration. The pump was supplied for evaluation with some settings which are inconsistent with UK healthcare norms:

- The pump could be turned off with a very short (0.1 s) press of the ON/OFF key. A time delay on switching off helps prevent accidental interruptions to therapy. The time delay can be configured between 0 and 31 seconds for this pump.
- KVO mode was configured ON, such that on pressing the STOP key during a delivery, the infusion does not stop but the flow rate changes to the KVO rate. It is more usual for KVO to be automatically triggered only when a preset volume to be infused has been completed. The manufacturer's advise it is possible to configure the pump conventionally so that KVO rate starts automatically on completion of the Volume To Be Infused, but the pump was not supplied with this configuration enabled.
- Air in line alarm bubble volume was configured to a default value of 250 µl (0.25 ml) which is higher than current minimum recommendations.
- On switching on the pump, recall of the previous infusion settings was configured to be inactive. A special combination key press was required to recall these parameters at switch on.

Photographs

Figure 2. Front of pump

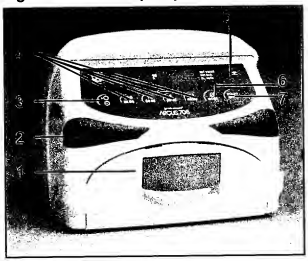
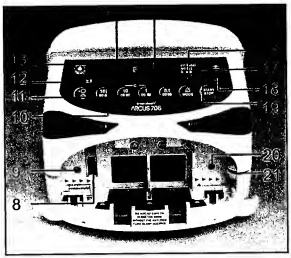


Figure 3. Front of pump, door opened



Key to Figures 2,3, 4 and 5

1. Front door
2. Global alarm indicator
3. Power On/Off key
4. Numerical input keys
5. Occlusion pressure alarm indicator
6. Mode/Mute key
7. START/STOP key
8. Anti-free-flow clamp port
9. Upstream pressure sensor
10. KVO infusion indicator
11. Drop detector indicator
12. External power supply indicator
13. Battery operation indicator
14. LED display (rate)
15. LED display (volume)
16. Battery alarm indicator
17. Drop detector alarm indicator
18. Air in line alarm indicator
19. Door alarm indicator
20. Downstream pressure sensor
21. Air detector
22. AC power connector
23. Pole clamp
24. Carry handle
25. Nurse call port
26. Drop detector port
27. Docking station power and data port

Figure 4. Back of pump

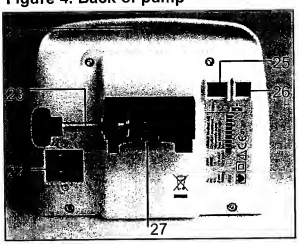
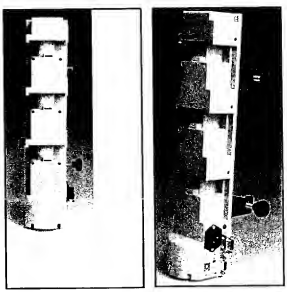


Figure 5. Docking station, 60M



Controls and Indicators

Panel controls and indicators

Small illuminated green icons on the front panel provide indication of: the type of power supply currently available - mains (12) or battery (13); whether drops are falling (11) and whether KVO is operating (10). Icons, which are illuminated red in an alarm state, indicate battery alarm (16), too few or too many drops (17), air-in-line (18), door opened during operation (19), and occlusion (5). High priority alarms are also accompanied by large flashing status indicators (2), positioned on the pump's corners so they can be seen from a range of angles. If configured to do so, these large red indicators also illuminate at the commencement of each infusion to confirm its start.

Infusion parameters and messages are displayed in the two 7-segment displays. These displays have serious deficiencies when rendering text. The running indicator is an unconventional scrolling dot on these displays which can cause ambiguity over decimal point position in rate or volume display.

Long term accuracy

Table 1. Long term accuracy results for Codan Argus 708

Flow rates tested	Greatest over delivery	Greatest under delivery	Accuracy at minimum flow rate
0.1 to 999.9 ml/h	+5.2% (at 999.9 ml/h)	-0.1% (at 125 ml/h)	-2.4 % (at 0.1 ml/h)

The Codan Argus 708 volumetric infusion pump was tested over the full range of flow rates offered by the pump, using the dedicated Codan IV set - IVIP 708 B86-Y. The other dedicated sets offered for this pump (IVIP 708 B88 (for blood infusions) and IVIP 708 V86) were not tested, as all these sets are made from the same materials (PVC) and should perform similarly in flow accuracy tests. The manufacturer recommends changing the administration set every 24 hours or after 2.5 litres of fluid has been delivered, whichever happens first.

Table 1 shows the results of flow rate accuracy testing. There is a small tendency for the pump to over deliver and the greatest over delivery recorded was +5.2% at the maximum flow rate of 999.9 ml/h.

Current measurement technology cannot adequately test very low flow rates, and they should be used with caution. Performance at such flow rates is erratic and sometimes inaccurate; an effort should be made to adjust therapy so that the lowest flow rate used with any critical infusion is 1 ml/h.

See figures 6 and 7 for fluid delivery profiles for Codan Argus 708 at 1 ml/h.

Figure 6. Long term accuracy at 1 ml/h over 24 hours

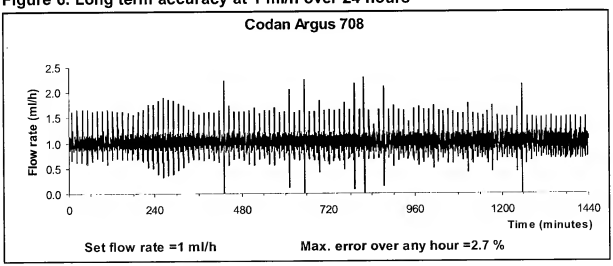
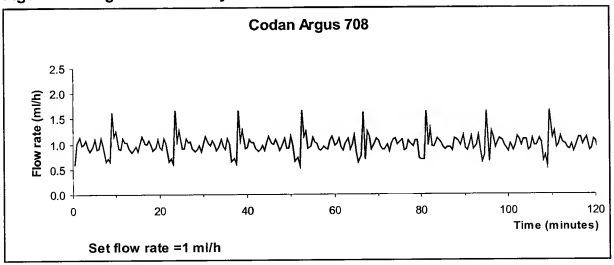


Figure 7. Long term accuracy at 1 ml/h over 2 hours



Short term accuracy and start up time

Table 2. Short term accuracy results for Codan Argus 708

Constancy index	Start up time
4.5 minutes	0.5 minutes

Short term accuracy (or minute-to-minute accuracy) of infusion pumps is expressed in terms of constancy index. The constancy index is defined as the shortest period of time over which the flow rate remains within 10% of the mean flow rate of 1 ml/h. The constancy index refers to the shortest half-life of drug that would be recommended for administration at this rate.

The constancy index of the Argus 708 volumetric pump is 4.5 minutes as shown in Table 2. Drugs with a half-life shorter than 4.5 minutes would not be recommended for delivery via this pump at low flow rates (1 ml/h and lower).

The startup time of the pump is very rapid (0.5 minutes) as is typical for volumetric pumps. Startup time is the time taken for the pump to start delivering steadily.

Volume to be infused

Table 3. Volume to be infused results for Codan Argus 708

Target	Actual
1 ml in 60 minutes	0.87 ml (-13% volume error) over 61 minutes
25 ml in 60 minutes	24.9 (-0.5 % volume error) over 60 minutes

These results (table 3) show usual levels of accuracy in delivering pre-set volumes of fluid at 25 ml/h. At 1 ml/h the inaccuracy in delivered volume was above 10%, with alarm being triggered between 6 minutes earlier and 1 minute later than expected.

Back pressure

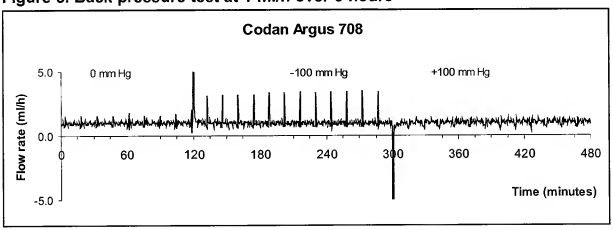
Table 4. Back pressure results for Codan Argus 708

Back pressure	Accuracy	Bolus (when back pressure changes)	Resumption time
0 mmHg	-0.3%	Not applicable	
-100 mmHg	1.6%	0.13 ml	
+100 mmHg	0.7%	-0.11 ml	4.5 minutes

The pump was set up to deliver at 1 ml/h against ambient pressure, +100 mmHg and -100 mmHg for two, three and three hours respectively. Changes in backpressure were achieved hydrostatically and the pump was not stopped during the pressure changes. Figure 8 shows the flow rate pattern for this test. Table 4 shows the transient highly increased or decreased flow during repositioning of the pump, and the time taken for normal flow to resume after pump lowering.

As can be seen from figure 8, the patterns of delivery change during repositioning of the pump and the minute to minute accuracy of the pump (defined earlier as constancy index) is affected adversely by this movement.

Figure 8. Back pressure test at 1 ml/h over 8 hours



Battery test

The pump is powered by a standard external AC source (230 V, 50-60 Hz) or external DC power supply (20 V/ 0.3 A). A rechargeable integrated NiMH battery can provide power when not connected to either of these. Sixteen hours are required to

charge the fully depleted battery. The battery charges automatically when the pump is connected to mains.

The Codan Argus 708 battery life was tested in the laboratory at 125 ml/h. At this rate the pump delivered accurately for 4 hours and 57 minutes, before the "battery empty" alarm was triggered which stopped the infusion. Three minutes later the pump automatically shut down. On reconnection to mains and pressing the "on/off" button (3) there is no immediate option for the user to restore and use the parameters of the previous infusion, interrupted by the depleted battery. To restore these parameters the user needs to power the pump on in a special way, namely by pressing simultaneously the power button and one of the numeric buttons - the "1" key. This action restores all the parameters of the interrupted infusion, including the rate of delivery, occlusion alarm pressure settings and total delivered volume. After reconnection to mains and correct recalling of the parameters the pump started delivering accurately within 1 minute. After reconnection to mains and powering the pump in the normal way and setting up the parameters of infusion again (125 ml/h rate) the pump also started delivering accurately within 1 minute.

Before the "battery empty" alarm which stopped the infusion, the low battery pre-alarm was triggered. This pre-alarm was given as an audible message together with the battery alarm indicator (16) showing red. This pre-alarm did not stop the infusion and the pump continued infusing accurately for the next 18 minutes triggering an audible alarm every two minutes until the "battery low" alarm stopped infusion. Three minutes later the pump automatically shut down. Earlier reconnection to mains (before complete shut down happened and after the infusion was stopped due to the "battery low" alarm) and an attempt to continue the infusion generated a fault code, F-52, which required powering the pump down. After powering the pump on and recalling the parameters as above, the pump continued infusing accurately.

Battery capacity can be checked at any time, either before or during infusion, by pressing the mode key (6) repeatedly until the message "CAP" is displayed in the left hand LED window (14); the right hand LED (15) will show the estimated remaining running time on battery, in hours and minutes.

Container height

There is no recommendation on the optimal (advisable) height of the fluid container relative to the pumping mechanism from the pump's manufacturer. The length of the recommended administration sets allows the user to place the fluid container more than a meter above the infusion site (there is no dedicated section of the set for loading into the pump, the anti-free-flow clamp can be positioned anywhere along the set length).

In the laboratory, the pump was set to run at 125 ml/h with the fluid container being normally positioned, with the drip chamber 30 cm above the pumping mechanism. At this setting the pump delivered accurately, close to the set flow rate (-0.3% error).

Two hours later the fluid bag was raised with the drip chamber positioned 80 cm above the pumping mechanism of the pump, which resulted in an increase of the flow rate by 3%. The pump delivered at these settings for a further 90 minutes, then the fluid bag was lowered down. According to the test protocol this part of the test should have been performed with the drip chamber positioned 50 cm below the drive mechanism of the pump, however that was not possible to achieve. The lowest achievable position of the drip chamber was 15 cm below the drive mechanism. Further lowering of the fluid container resulted in the "drop alarm" which stopped the infusion. Moving the fluid container up and down relative to the pump affected the flow rate, but the accuracy remained within the manufacturer's claims. Users should remain aware however, that in clinical conditions effort should be made to ensure that the fluid container is always appropriately positioned (i.e. the drop chamber should be around 30 cm above the pumping mechanism).

Patient side occlusion

Patient side occlusion alarm pressure settings are adjustable by the user from the front panel and can be changed in 10 steps of 75 mmHg, between 75 and 750 mmHg. Additionally, the neonatology mode (a configurable option) allows a patient side occlusion pressure limit lower than for standard applications (the lower setting is 45 mmHg). The default occlusion alarm pressure level is 525 mmHg. The pump always uses the default setting on switching on, unless recall settings is performed. The occlusion alarm times at 1 ml/h are shown in table 5.

Table 5. Patient side occlusion results at 1 ml/h for Codan Argus 708

Average time to alarm at 1 ml/h	Average post occlusion bolus
4 minutes and 54 seconds	0.02 ml

The pump was tested to establish the speed of response to patient side occlusion and bolus volume on release of occlusion. The occlusion alarm pressure was set to 75 mmHg - the minimum occlusion alarm pressure setting for general applications. Neonatology mode occlusion alarm pressure can be set lower, but this was not tested as part of this evaluation. Downstream occlusion was detected by the downstream pressure sensor (20) and the alarm was given as an audible tone together with illumination of the occlusion alarm icon (5) and flashing of the global alarm indicators (2). The downstream pressure indicator (5) gives an estimate of pressure in line on a scale from zero to the alarm pressure level in five steps. When running in the neonatology mode the current pressure in line is displayed in mmHg, alternating with the display of the rate and volume infused on the displays (14) and (15). Figures 9 and 10 demonstrate the change in time to alarm and post-occlusion bolus volume with respect to flow rate. The measurements were taken for three flow rates: 1, 5 and 25 ml/h.

Figure 9. Time to alarm on occlusion

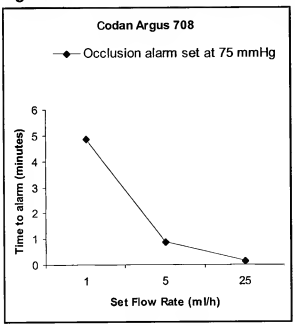
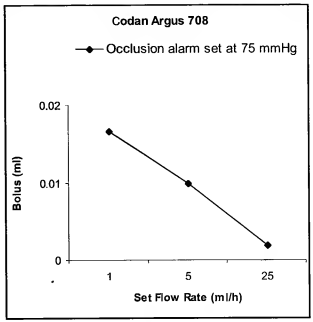


Figure 10. Bolus released after occlusion



The Codan Argus 708 pump is provided with an anti-bolus function to minimize the post-occlusion bolus. After detection of an occlusion, the pump mechanism runs backwards to reduce the build up of pressure in the line. The post occlusion bolus measured during testing at various rates was small, with one negative bolus, i.e. suck back, recorded on release of occlusion when infusing at 25 ml/h. The manufacturer warns users about the possibility of excessive bolus reduction by the pump which might result in patient blood flow back into the tube.

Measurements of in-line pressure when the pump detects an occlusion, indicate that the pump triggers the occlusion alarm when the pressure in line is lower (43 mmHg) than the nominal occlusion alarm pressure (75 mmHg). In one of two cases it was recorded that the back off mechanism reduced the pressure in line below zero, thus introducing a negative pressure in the line. Negative pressure in the line might cause blood to be drawn back into the cannula when an occlusion is released, which is highly undesirable. The back off characteristics are configurable and can be configured off, however disabling this function will result in an increase of the post-occlusion bolus volume size.

Fluid side occlusion

The pump was tested to determine the speed of response to an occlusion between the fluid container and the pump. The Codan Argus 708 has an upstream pressure sensor (9) which can be enabled or disabled from the configuration. The upstream pressure alarm level is fixed in the pump configuration (value is not given) and can not be changed by the user (it can be disabled from the configuration, however).

Upstream occlusion can also be detected by the drop detector, when the pump detects a deviation in the number of drops from that expected for the set flow rate.

This is generally considered to be a more reliable method of detecting upstream occlusion than an upstream pressure sensor, and this was confirmed by subsequent tests without the drop detector. Drop detection is also a configurable function and can be enabled or disabled. In the pump supplied for evaluation upstream occlusion detection and drop detection were both enabled.

At maximum flow rate (999.9 ml/h) an upstream occlusion immediately below the drop chamber was detected almost instantaneously. In most tests this was indicated by an upstream pressure alarm, but on a few occasions the alarm was triggered by the drop detector. On detection of occlusion the infusion is stopped and the pump generates an audible alarm plus either drop detector alarm indicator (17) or illumination of the red indicator for upstream pressure alarm (a vertical bar on the occlusion alarm diagram (5)). The global alarm indicators (2) flash red as well. No additional message on the cause of the alarm is given by the pump.

The average time to alarm at 1 ml/h was 14 minutes and 53 seconds with the alarm triggered by the drop detector. However when the line was not occluded fully the upstream occlusion was not triggered for 3 hours when delivering at 1 ml/h, resulting in unrecognised underdelivery (the pump incremented and displayed the infused volume according to the set rate and the elapsed time).

When the drop detection function was configured off, the pump ran at 1 ml/h rate with a fully occluded line (just below the drip chamber) for 5 hours. No alarm was triggered and no fluid delivered. The pump indicated running with the volume infused incrementing according to the set flow rate. At maximum flow rate (999.9 ml/h) upstream occlusion is very rapid and triggered by the upstream pressure detector. It is, therefore, advisable to use the drop detector in order to detect upstream occlusion reliably. Codan supply the pump with drop detector, and it is only disabled on customer request. Both BIME and Codan recommend it is used.

Air-in-line testing

The Codan Argus 708 air detection system operates an ultrasonic air bubble detector, and provides both single bubble and cumulative air volume detection. The single air bubble volume is set in the pump configuration and can be chosen between 50 and 1000 µl (the default value is 250 µl, which is rather high for the UK health market). Detection of cumulative air volume can be either enabled or disabled in the configuration. If enabled the pump can be set up to detect a cumulative volume of air between 100 and 2000 µl in 50 µl steps with time period set between 8 and 64 minutes in 8 minute steps (these are all configurable parameters and can only be changed by an authorized person). The default value for the cumulative air volume is 1000 µl in 32 minutes. Accumulating air-detection was not tested in this evaluation (by default, it is configured off).

The pump was configured to detect a single air bubble volume of 50 µl (cumulative air-detection was configured off). A single air bubble of 50 µl was introduced into the

administration set upstream of the pump and the pump was set running at 125 ml/h – a typical rate for a volumetric pump. The pump was not able to detect a 50 µl air bubble reliably. An air bubble of 100 µl was detected reliably by the pump when set to detect an air volume of 50 µl.

On detecting an air bubble the pump triggers an air-in-line alarm, which is given in the form of the global alarm indicators (2) flashing red, an audible intermittent alarm sound and illumination in red of the the air-in-line alarm icon (19). The infusion stops when alarm is triggered. If a decision is taken to re-prime the line, care should be taken to disconnect the patient first. These important safety precautions are not stated separately in the user manual. The set should never be connected to the patient during priming.

Training

The pump's training package consists of an End User Workbook and a User Training software package. The manufacturer also offers a "train the trainer" workshop, which is a half a day session for experienced users of the pump. The notes of the workshop were offered for the evaluation. The workshop focuses on legislation, importance and goals of training in using infusion devices and goes in detail through typical infusion therapy practice, terminology and processes, including syphonage, free flow, air entrapment, occlusion, extravasation, infiltration, phlebitis, priming and purging.

The End User workbook includes a handout (A4 size), which provides detailed, step by step training on the pump and its functions. The material in this guide is designed for use by an individual user at his/her own pace and should be used with a pump. The information in this training guide is grouped into logical sections and accompanied by clear labelled diagrams and typical displays. Each section ends with a self assessment task which allows a user to practise the function learned. The guide is complemented by an index list, a comprehensive glossary and a list of website links.

The "User Training" software package offered by Codan is an excellent demonstration package which guides a user through all the necessary procedures in working with the pump in a logical, interactive and user friendly way. Instructions are accompanied by the clear illustrations and animated demonstrations. Examples of possible incorrect procedures are given as well. This package is for demonstration purposes and the user cannot use it to perform practical tasks.

The whole training package for the Codan Argus 708 pump is well written and well structured. It provides all the necessary information for competent use of the pump.

User assessment

The manufacturer of the Codan Argus 708 infusion pump was asked to provide a list of centres currently using or trialling the pump. Two NHS Trusts were recommended. Users from these trusts were sent the questionnaires to fill in. Eight responses were received (all from one trust). The users who responded had been using the pump between 4 and 12 months. Initial training on the pump had been mainly provided by the manufacturer and/or by a trust-based trainer.

The questions in the questionnaire were grouped to provide feedback on the various features of the pump including a general view on the appropriateness of the pump (weight, size, ease of moving around, battery life and robustness), ease of setting up infusion parameters and monitoring the infusion. Users were also given an option to express their general opinions on the pump, suggest improvements, and report on any unnecessary features.

The distribution of user responses is given in figure 11 and individual user comments are transcribed below.

Questionnaire survey results:

The coverage of the user instructions
- it did take a few months to master, by playing with it

The loading procedure for set
- can be a little fiddly when using for the first time

The ease of navigating the control panels
- screen is too small

The visual display
- screen too small

The alarm tone was
- too loud sometimes

Safeguard against tampering
- patients can tamper with buttons – needs lock
- patients are able to press buttons, e.g. will silence machines, they need a locking device

The ease of cleaning the pump
- mainly easy, but fiddly around carrying handle

List any features that they would like to see but which are not present on the pump

- locking mechanism – to prevent patients tampering with device
- locking system to prevent patients from tampering with machine
- A code could be present to prevent patients or other users tampering with the device, who have not had sufficient training

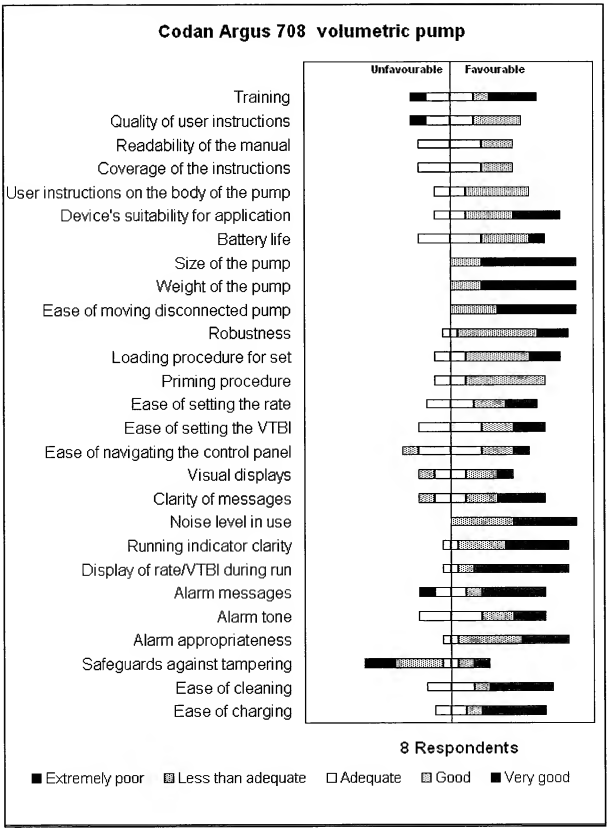
BIME Note: A keypad lock function is available in this pump, but it is a configurable feature and is not available if configured off. In the pump supplied for the evaluation the keypad lock was configured off.

An additional comment on using the pump was given by one user:

- visual indicators for mode selection should be bigger + clear

Figure 11 below summarises the users responses.

Figure 11. User assessment results for the Codan Argus 708 pump



Usability assessment

Heuristic evaluation

The laboratory based assessment of usability of the Codan Argus 708 volumetric pump was conducted using a task list comprising common required procedures for this type of pump. The task list was constructed by a combination of interview with appropriate users, and by inspection of the history logs of recently clinically used pumps of this type. The latter step is an innovation to the testing procedure, and provides significant insight into users' achievements with and to some extent, expectations of the pumps. These logs can provide further information on user error and may be exploited further in forthcoming evaluations. The task list was then worked through in the usual manner, according to the protocol, by three trained evaluators. The task list included typical tasks, as well as dealing with common events including an air in line alarm and an occlusion alarm. Evaluators were also instructed to make a free investigation of functions provided by the pump. Usability problems were noted as the tasks were completed, and these were then editorially combined into a full list of non-overlapping problems. This final list was then rated for severity by the three evaluators and also scored against a list of 'heuristics' (rules) for good usability.

Previous evaluations have used a system of assessment against 15 possible categories of heuristic violations. Recently published work [1] demonstrates that this system was difficult to apply consistently, and hampered by lack of agreement about the meaning of each category title. As the intention of this heuristic evaluation is eventually to produce a system whereby pumps can be compared for usability, using a few simple scores, this was seen as a weakness of the system. The list of heuristic violations was therefore revised, and redefined (see Appendix for new list versus old list). The scores given below are against the new list, therefore, and should not be compared with previous findings on other pumps.

Table 6 shows the total number of usability problems identified and the number of heuristic violations. The spread of problems in terms of severity is shown in table 7, determined by mean severity rating from the three evaluators. Two problems were rated 'catastrophic' (average severity rating > 3.5), and, with those rated as 'major' (average severity rating > 2.5), are described in more detail in table 8 .

Table 6. Total number of usability problems and heuristic violations identified

System	Number of problems	Number of heuristic violations
Codan Argus 708	43	151

Table 7. Summary of severity ratings for the usability problems identified

System	Cosmetic problems	Minor problems	Major problems	Catastrophic problems
Codan Argus 708	4	24	13	2

Table 8. Problems identified for the Codan Argus 708 volumetric pump

Usability problem (see manufacturer's comments p. 80)	Severity
If the pump goes into standby, due to user delay, whilst setting the rate then pressing the dual function alarm silence key also operates the mode function; the user finds themselves in an unwanted menu with no way back to the rate setting screen. The silence operation should not simultaneously operate the other "dual" function.	4.0
When the pump is paused, switch off (as configured) is almost instantaneous (0.5 s) and can be achieved by accidental press. (The rate and other parameters are configured to clear on switch OFF, so the consequences of this error are not easily reversible.)	3.7
Line label can be changed (e.g. Antiblot to Nannitol) with the pump on pause with no warning and with no change to ml total or ml inf. On restarting, it is the same infusion continuing with a completely different drug label.	3.0
When you press STOP, the pump does not stop, it goes into KVO rate. Conventionally KVO is a rate that operates when VTBI has been delivered but before user has intervened and stopped the pump. STOP should mean stop. This can be configured to behave conventionally.	3.0
Alarm silence key is also the mode key. Bad dual function. This is further complicated by the mode function having 10 possible subdivisions of function.	3.0
The 7 segment display provided for showing text and numerals is not adequate for this purpose. E.g. line label appears as "Antiblot" (meaning Antibiotic).	3.0
The complex configuration makes the pump too flexible, its performance in different configurations can be very different, and it is potentially confusing to use therefore.	3.0
The display of rate is not available at the point the user is required to press START.	3.0
100.0 ml/h can be misread as 1000 ml/h - the nearby flashing decimal point on the adjacent display can cause the user to disregard this decimal point.	3.0
If the standby alarm goes off during an attempted change of rate during a run, the START/STOP key has an unclear function and the user can be uncertain whether new rate is in effect. In fact it silences the standby alarm only. The new rate is not implemented. (The user is allowed a limited period to confirm the new rate, after setting it.). If no standby alarm occurs, the START/STOP key implements the new rate.	2.7
Having set 91h 06 mins before setting rate, this info now seems to be lost	2.7
Hidden features, such as recall last settings are difficult to find	2.7
No text messages on screen to guide setup or resolution of alarms	2.7
The alarm icons are not clear, they are sometimes only partially lit, are unconventional and their meaning not obvious.	2.7
The scrolling decimal point (used to indicate the pump is running) can confuse the display of volume infused.	2.7

Overall the system was found to offer a wide variety of features from within the configuration, but was limited by its rudimentary display. The two findings which were judged to be in the most severe band were: 1. simultaneous action of alarm silence and mode functions, so that use of the alarm silence key boots the user out of the required menu into another having little meaning in the context, and 2. the fact that the power off button is instantaneously effective as configured. This, combined with the configured clearing of previous displayed settings by default, leaves the user vulnerable to accidental and/or unnoticed switch off, or loss of parameters on battery exhaustion, without evident means of reversing the loss.

The latter problem would not arise if the pump was configured differently. This was also a significant finding of the usability assessment. Several other parameters were set for values that were unfamiliar to UK practice, for instance, KVO delivery STARTS when STOP is pressed. These highly flexible configurations are intended to make pumps more marketable to a wider range of customers. Ironically, a more limited, safety oriented configuration would have scored better for good usability features.

This finding complies with NPSA and MHRA advice, advocating standardisation of infusion pumps in Trust settings; subtle changes in pump functionality that are not obvious to the user, but are configurable through the technician menu, can lead to hazardous confusion of users. Codan also note that configurations of pumps for clinical use would be discussed fully with Trusts before being set up, thus alleviating those problems noted here where configuration was contributory.

Communicating with and receiving messages from pump

Several of the problems were caused by a lack of clear instruction, either from the manual or on the display of the pump. For instance the use of non-standard, unintuitive icons without explanatory labels to indicate alarms, unpredictable layout of the manual and poor rendering of text messages on the 7 segment display. In general the manual was found to have a number of errors, and to be difficult to follow; Codan state the manual is being redrafted.

The display of rate and volume were sometimes misinterpretable due to the scrolling decimal point, which is used as a running indicator. Most worryingly, the rate is not displayed at the time that the start/stop key is pressed due to use of the display for other messages at this time. This removes a critical checking opportunity, and could lead to confirming an error.

Communicating instructions to the pump was also found to be hampered in some instances by the simple, and very compact interface. Several keys have dual functions; in some cases these dual functions were not predictable, for instance, the start/stop key could be used to silence an alarm leaving the user uncertain whether just the alarm silence had been implemented or whether the pump had also been re-started. Other useful functions involved combination key presses; these are notoriously difficult to remember even when properly trained.

The lack of clear text messages to provide instruction or explanation of alarms is a significant disadvantage, when compared with the facilities commonly provided on current pumps using LCD displays. Alarm tones were also sometimes found to have an inappropriate level of urgency.

Highly flexible configuration
Whilst the provision of additional features is regarded by most users as an advantage, the ability to reconfigure pumps so as to behave entirely differently for a given sequence of key presses also leads to increased opportunity of use error. Users familiar with one configuration may fail to notice, for instance, that KVO is configured off, that a drop detector, essential for reliable detection of upstream occlusion alarms, is not fitted, that a single brief key press turns the pump off and loses the infusion parameters.

Standardisation of equipment is only an effective safety measure if the equipment behaves predictably to type.

Physical design features
Most of the physical features which were criticised provided more minor problems; in general the physical attributes of the pump were commended, particularly the small size and comparative lightness.

It was found that the near vertical control panel led to a tendency for the pump to roll away from the user when keys were pressed and the clamp and cable could interfere with each other, also the drop detector has no effective parking place so might get damaged in transport.

Some accessories were not tested during the evaluation.

Positive points
Heuristic evaluation is necessarily a negative process involving criticism of features which are sub-optimal. The usability testing protocol has recently been modified, therefore, in order to include assessment of positive attributes of the pump. They are listed here for information:

- Loading the set and anti free-flow clamp is easy
- Flashing red alarm lights are very good, well positioned and attention grabbing
- The pump is quiet in operation
- The docking station has a fairly positive feel when attaching pumps, and pumps do not immediately fall away when being detached
- The pump is a nice clear colour and the red lights are attractive
- The pump is light and easy to handle using the top handle

- The basic alarm tone is loud and prominent
- Rapid occlusion alarm when restarted into an occluded line
- Colour matching of the red anti-free-flow clamp and the red recess behind the door makes it easy to see what goes where
- The anti-free-flow clamp automatically closes on removal from the pump
- Warning in the door of the pump - do not attempt to close the door etc. - well positioned and could help avoid accidents. Perhaps a picture would be better
- Instructions included on the side of the pump
- There is an alarm when the pump has finished delivering VTBI

Summary of usability assessment

The Codan Argus 708 is a pump with a basic user interface that has some usability problems, some of which would decrease with familiarity. Some of the difficulties arise over features which are unconventional, or unconventionally configured. Also the text message display is not adequate, leaving the user in the dark occasionally on how to recover errors or proceed with required procedures.

Numerous good features were also identified, and the pump's attractive design and compact size were striking examples of these. The pump is comparatively low cost and has a level of sophistication to match the price tag. For familiar users with only routine requirements the pump would probably perform well and safely. Codan are introducing a modification to the door of the pump on all pumps to be completed by the end of September 2006, which will prevent the particular misload noted in this report (see Faults during testing).

Manufacturer's data

Product data

Manufacturer	CODAN/Argus Aarestrasse 13, Heimburg, Switzerland CH-3627 Tel:41334381338 Fax:41334371141 www.codanargus.com, info@codanargus.com
Supplier	CODAN Ltd Eastheath Ave, Wokingham, Berkshire, UK RG41 2PR Tel: 0118 978 3663 Fax: 0118 977 6274 www.codanargus.com, info@codanmed.co.uk
CE marking on product?	Yes, CE 0120
Notified body	MDD 93/42/EEC directive
Manufactured to Standard	ISO 13485, ISO 9001, EN 60601-1-1, EN 60601-1-4, EN 60601-2-24, EN 61000-3-2, EN 61000-3-3, EN 60601-1-2
Country of origin/manufacture	Switzerland
Price (ex VAT)	£1,850 List price Solution Set with anti-free-flow (AFF) clamp, 373161, Price £1.24 Blood set with AFF clamp, 455550, Price £1.36 Primary Set with AFF clamp, 373194, Price £1.83 Epidural Set with AFF clamp, 373195, Price £1.50
Size (H x W x D)	160 mm(H) x 190 mm(W) x 130 mm(D)
Weight	2.0 kg
Power Supply	Yes, standard mains plug
Battery operation	Yes
• battery capacity	6 hrs at 25ml/h
• battery charging facilities	Mains
Facilities	
• pumping mechanism	Peristaltic
• administration sets	CODAN AFF Only
• accessories	Various, available upon request: external drop detector, rail combi clamp, bottle holder, user manual and training pack
• flow rate range	0.1 - 999.9 ml/h
• flow rate increments	0.1, 1, 10 or 100 ml/h
• programmable infusions	Yes
• drug dosing protocols	Yes, available
• volume to be infused facility	Yes
• volume infused indicator	Yes
• KVO rate	Optional
• claimed accuracy	+/- 5 % set dependant
• occlusion pressure	Yes, up and downstream (75 - 750 mmHg)
• alarms and alerts	air in line, downstream occlusion, upstream occlusion, battery empty, door open, flow error (if drop detector in use), end of infusion, safety standard, technical failure, stand-by, battery low
• tamperproof	Yes, data lock facility

Product data (continued)

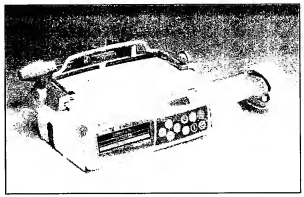
• type of display	3 Line, LED
• air in line detection	Yes
• type of infusion fluids	Blood, Crystalloids, Colloids, TPN
Nurse call facility	Yes
Computer interface	Yes, RS232
Mounting method	Pole, Docking station
Protection against fluid ingress	IPX 2
Electrical safety classification	Class IIb
Model identification	
• Serial number	19.111
• Software version number	V4.3

Product Support

Servicing and training	CODAN Ltd Number 1, Eastheath Ave, Wokingham, Berkshire, United Kingdom, RG41 2PR Tel: 41334381338 Fax: 41334371141 www.codanargus.com info@codanmed.co.uk
Provisions for staff training	
• initial in-service training	Fully accredited British Association of Critical Care Nurses (BACCN) training satisfying Clinical Negligence Scheme for Trusts (CNST) level 3
• follow-up in-service training	As Above
• first line maintenance training	Provided free of charge (FOC), numbers to be agreed
• full service/maintenance training	Provided FOC, numbers to be agreed
Warranty	24 Months
Maintenance provisions	
• recommended service interval	Every 24 months
• contract service/maintenance	Details available upon request
• temporary loan of equipment	Available at supplier's discretion
Spare parts	
• spares availability	Immediately
• cost of parts and materials	Prices available on request
Accompanying manuals	
• user manual	Free of charge with purchase of pump
• technical/service manual	Additional copies FOC Free of charge if training is purchased. Additional copies FOC.

B. Braun Perfusor summary

Brief description



The B. Braun Perfusor Space syringe pump offers extensive features to meet the needs of both general ward use and critical care applications. It is designed to be used on its own or in combination with its sister pump, the B. Braun Infusomat Space. Both pumps can be fitted interchangeably in the B. Braun Space Station to facilitate control and monitoring of multiple infusions, while additionally offering power to multiple pumps using a single cable. The Space Station also features advanced networking facilities and an enhanced alerting system using large warning lights. As with any new device, the pumps will appear unfamiliar to new users but the overall Space concept has clearly been developed with a user centred approach and the clear messages and logical programming steps promote safe use.

Advantages

- Small
- Lightweight
- Good modular system; uniform user interface with Infusomat Space volumetric pump
- User friendly design
- Clear instructions and excellent on screen messages
- Good battery life and power management
- Dose limiting software is offered
- Bar coding will be offered
- Service/repair is engineer friendly with good after-sales service
- Clinical Information System (CIS) connectivity
- Piston brake prevents syphoning during set up

Disadvantages

- Syringe placement is fiddly
- Motorised syringe loading system feels slow to some users
- Similarity of appearance between Infusomat and Perfusor pumps could lead to confusion and the wrong pump being delivered to the bedside from stores
- The end of syringe alarm for the BD50 is triggered by pressure and inappropriately causes backoff to occur
- No message on the pump to ensure patient disconnected during prime
- When the pump door is opened, the main display and control keys are out of sight
- Loading the syringe barrel flange incorrectly in the pump and confirming the syringe size suggested by the pump can cause a 30% under-delivery error

Faults during testing

Occlusion testing uncovered a bug in the pump software. When priming, or delivering a bolus the pump temporarily sets the occlusion pressure to its maximum value to avoid nuisance alarms resulting from the rise in line pressure during these periods of high flow rate delivery. It was found that the prime function failed to return the pump to its normal occlusion pressure setting on completion of the prime, the setting became 'stuck' at the maximum value (but the screen icon displaying pressure indicated whatever the user setting had been). This bug led to excessively long occlusion detection delays, but only when the prime had been previously used. The software was corrected by B. Braun and the corrected version is being distributed as an upgrade to all users.

During some of the 24 hour flow tests at 1 ml/h, momentary disruptions to smooth fluid delivery were seen. B. Braun have not been able to reproduce this measurement. (see manufacturer's comments p. 80).

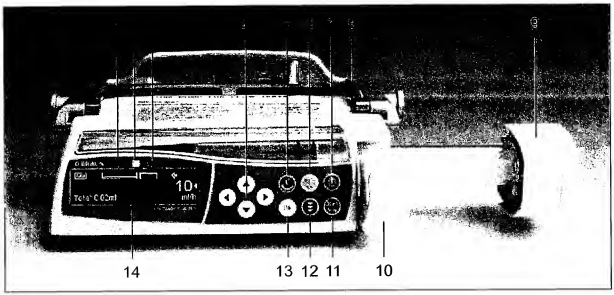
A small green plastic hook on the Space Station for supporting the Infusomat Space administration set was accidentally broken during the evaluation. It was easily replaced by B. Braun.

Main features

Feature	Detail
Power supply	via B. Braun SpaceStation or mains adaptor (100 - 240 V AC, 50/60 Hz); 11 - 16 V DC via external 12 V supply or via SpaceStation; NiMH rechargeable battery
Disposables	The pump can be used with all major syringe brands including BD, TYCO, B. Braun Perfusor and Omnifix, Monoject and Terumo
Flow rate range	0.1 to 200 ml/h default; 0.01 to 999.9 ml/h configurable; bolus rates up to 1800 ml/h (max. rates are configurable)
Pump mechanism	Stepper motor
Occlusion detection	Nine levels from 0.1 to 1.2 bar (75 to 900 mmHg)
Alarms and alerts	Comprehensive
Price (ex VAT)	£ 2200
Manufacturer	B|Braun Melsungen AG
CE Marking	Yes
Notified body	0123 TÜV
Certified to standard	IEC 60601-1-2; IEC 60601-2-24; EN 55011, BS EN1789:1999

Photographs

Figure 12. The B. Braun Perfusor Space syringe pump



Key

1. Yellow LED: pre-alarm/reminder
2. Green/red LED: Infusing/alarm
3. Blue LED: SpaceControl connection
4. Arrow control keys
5. Cancel / zero / step back key
6. Bolus key
7. ON / OFF key
8. Pole clamp + carry handle
9. Drive head
10. Syringe holder
11. Start / stop key
12. SpaceControl key
13. OK / confirm key
14. Back lit graphic display
15. Battery compartment
16. Port for power supply / other functions
17. Port for SpaceControl
18. SpaceStation with cover and carry handle
19. Status / alarm display
20. Guide hook for infusion lines
21. Knob to unlock pumps

Figure 13. Rear view of pump

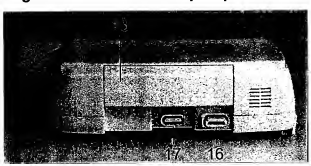
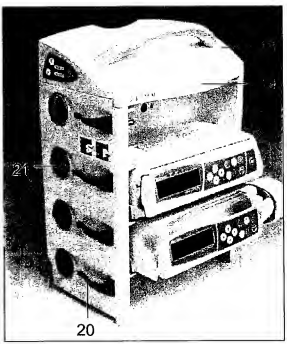


Figure 14. SpaceStation + pumps



Long term accuracy

Table 9. Long term accuracy results for B. Braun Perfusor Space

Flow rates tested	Greatest over delivery	Greatest under delivery	Accuracy at minimum flow rate
0.1 to 200 ml/h	+ 1.8 % (at 1 ml/h)	- 1.5 % (at 1 ml/h)	- 4.1 % (at 0.1 ml/h)

The Perfusor Space was tested over the full range of available flow rates from 0.1 ml/h to 200 ml/h. This default configuration was used in testing, but flow rates from 0.01 ml/h to 999.9 ml/h can be allowed by configuration changes. Bolus flow rates of up to 1800 ml/h can be configured.

B. Braun Omnifix 50ml syringes were used for the majority of flow testing, and six alternative syringes were also tested: B. Braun Omnifix 30 ml, B. Braun Omnifix 20 ml, B. Braun Omnifix 2ml, BD Plastipak 50 ml, Terumo 50 ml and Monoject 50 ml.

Excellent long term accuracy was achieved in all tests, with small errors centred around zero. Figures 15 and 16 show flow at 1 ml/h plotted over 2 and 24 hours.

A slightly larger error (- 4.1 %) was seen for flow at 0.1 ml/h. Such inaccuracy is to be expected if delivering from a large volume syringe (50 ml), as in these tests. Very low flow rates should therefore be used with caution since performance for any pump is more erratic at such low rates. Efforts should be made to use smaller syringe sizes at lower flow rates, and/or avoid low flow rates when clinically possible. Dilution used in conjunction with a higher flow rate may sometimes be an option, though the risks of dilution (e.g. contamination, miscalculation or inappropriate diluent) should also be considered.

Figure 15. Long term accuracy at 1 ml/h over 2 hours

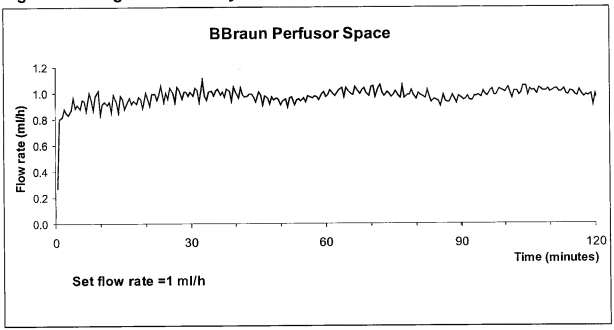
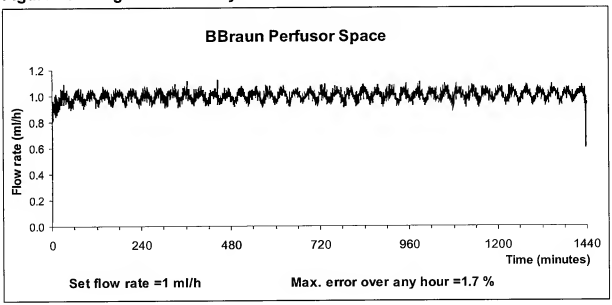


Figure 16. Long term accuracy at 1 ml/h over 24 hours



Short term accuracy and startup time

Table 10. Short term accuracy results for B. Braun Perfusor Space

Constancy index	Startup time
4.5 minutes	2 minutes

Short term accuracy of infusion pumps is expressed in terms of constancy index. Constancy index can be translated as the shortest half-life of a drug that would be recommended for administration with this pump. Constancy index is measured at 1 ml/h and indicates the minimum period of time over which the flow rate remains within 10% of the mean flow rate. It is a measure of the short term variability of flow patterns - small values of constancy index are better than large.

The constancy index for the Space Perfusor was not consistent, with a worst case of 4.5 minutes. This is not as good as the values measured for some other current, typical syringe pumps.

Several 24 hour tests using a variety of syringes showed momentary drops in fluid delivery. This may be of clinical significance when delivering very fast acting drugs and has been reported to B. Braun for comment. These flow discontinuities contribute to the worse than average constancy index, although the trace also shows periodic cycling for this pump, dictated by the drive system. This has a cycle time of about 30 minutes (at 1 ml/h) and does not significantly affect short term accuracy.

Startup time is a measure of the time taken at the start of an infusion for flow rate to stabilise at the set rate.The startup time for the B. Braun Perfusor Space is 2 minutes using the B. Braun Omnifix 50 ml syringe. This is excellent. A startup time of

8 minutes was seen when the 50ml BD Plastipak syringe was used, and the 50 ml Terumo syringe produced the longest start up time of 12 minutes. Syringe brand has a significant effect on start up time due to the differing materials and tolerances used in the manufacture of the various syringe brands.

Startup time is very significantly affected by priming the pump to take up slack in the drive mechanism before the pump is started. The motorised loading mechanism in the B. Braun Perfusor pump is reported to take up slack automatically, but this will not necessarily compensate for variable levels of slack and/or stiction present in the syringe brand used. Priming the pump is not specifically recommended by B. Braun; BIME results indicate that the pump should be primed before all infusions to achieve the fastest startup performance.

Whether or not priming is used, B. Braun (and BIME) recommend that the drug should not be connected to the patient until the syringe is fully loaded in the pump.

Volume to be infused

Table 11. Volume to be infused results for B. Braun Perfusor Space

Target	Actual
1 ml in 60 minutes	0.98 ml (-2.4 % volume error) in 60 minutes
25 ml in 60 minutes	25.03 ml (+ 0.1 % volume error) in 60 minutes

These results indicate good, reliable delivery over specified time periods, even when volume demand is low.

Back pressure

Table 12. Back pressure results for B. Braun Perfusor Space

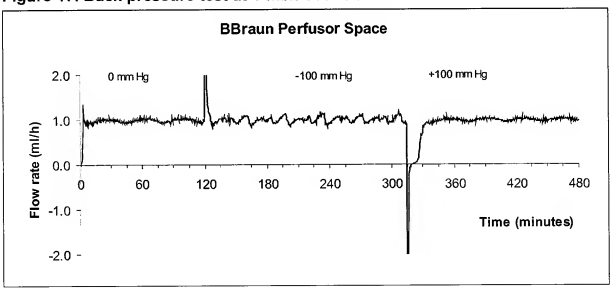
Back pressure	Accuracy	Bolus (when back pressure changes)	Resumption time
0 mmHg	- 1.1 %	Not applicable	
- 100 mmHg	- 0.1 %	+ 0.38 ml	
+ 100 mmHg	- 0.8 %	- 0.75 ml	17.5 minutes

The pump was set to deliver at 1 ml/h for eight hours. Initially the pump was aligned level with the cannula outlet. After two hours, the pump was raised by 136 cm to simulate a drop in back pressure of 100 mmHg. After a further three hours, the pump was lowered by 272 cm to increase the back pressure to 100 mmHg above ambient. The pump was not stopped during repositioning. Figure 17 shows the flow rate of the pump throughout this eight hour test.

The disruptions visible on the graph demonstrate the potential hazard to a patient on moving a pump vertically in relation to the venous access site while it is delivering. When the pump is raised, a bolus is delivered to the patient, resulting in a temporary overdose. When the pump is lowered, fluid delivery temporarily ceases due to the backward flow of fluid in the administration set.

The time taken to restore normal delivery after an increase in back pressure (the resumption time) is rather long for this pump, and consequently there is a significant deficit in fluid delivery in the period following the pressure increase. Interestingly, the short term flow variability deteriorates during the period of reduced pressure. This is a common finding with infusion pumps of both volumetric and syringe type; it is not proven whether this particular effect is deleterious to patients. Users should be aware of the possible hazard to patient of the combined effects, however, and avoid moving the pump with relation to the height of the cannula, during an infusion.

Figure 17. Back pressure test at 1 ml/h over 8 hours



Bolus volume accuracy

The pump offers three modes for bolus delivery: manual, volume preselection, and rate calculation. In rate calculation mode both preselected volume and delivery duration are set and the required flow rate is displayed. Results for manual and volume preselection modes only are presented here. The flow rate for bolus delivery can be configured from 1 - 1800 ml/h, with a configurable default rate of 400 ml/h.

In manual mode, demand volumes of 0.1 ml, 1.0 ml and 5.0 ml were used for the tests and delivery rates of 100, 400 and 1800 ml/h were used for these volumes respectively, to allow an accurate demand to be administered in a reasonable time.

In volume preselection mode the default bolus delivery rate of 400 ml/h was used for all demand volumes.

Table 13. Bolus volume accuracy results for the Perfusor Space

Demand volume	Bolus mode	Bolus rate	Average delivery 5 measurements	Greatest single error of 5 measurements
0.1 ml	Manual	100 ml/h	0.10 ml	10 %
1.0 ml	Manual	400 ml/h	1.01 ml	3.0 %
5.0 ml	Manual	1800 ml/h	4.91 ml	-3.2 %
0.1 ml	Volume preselection	400 ml/h	0.10 ml	10 %
1.0 ml	Volume preselection	400 ml/h	1.00 ml	1.0 %
5.0 ml	Volume preselection	400 ml/h	5.00 ml	0.4 %

Table 13 shows the results of bolus volume accuracy testing. Performance is excellent for all demand volumes in both manual and volume preselection modes. The measured errors in manual mode are partly dependent on operator skill at demanding the correct bolus volume.

The errors are largest for the 0.1 ml bolus in either mode, and this is to be expected as the demand is so small. A 10% (or 0.01 ml) maximum error represents excellent performance in this test.

Battery test

The Space Perfusor has an integrated Nickel Metal Hydride (NiMH) battery. The battery life was tested from fully charged and the pump operated accurately at 1 ml/h for 20 hours 5 minutes. Half an hour before shutdown, a 'battery near empty' alarm was triggered, which could be muted. The 'battery empty' alarm stopped fluid delivery and a message advised the user to connect the pump to the mains power supply. On reconnection to mains, the pump is put in standby mode and the previous infusion can be resumed by pressing the start key, with previous rate and volume infused data being preserved. If however the user does not reconnect to mains within 3 minutes of the battery empty alarm, the pump shuts down fully and on subsequent reconnection to mains the previous flow rate and volume infused were not offered in the pump configured for evaluation.

During normal infusions, the battery level indicator is shown as a symbol on the main display with zero to three bars lit within a battery shaped symbol. There is also a menu option showing the estimated remaining time.

The pump features a 'battery maintenance' facility whereby the pump will automatically prompt the user to periodically carry out a battery discharge/recharge cycle while not in use. This is said to significantly increase the working life of the battery and is therefore a welcome feature. It has been introduced so that it takes a simple key press to carry out when prompted (about once per month) and yet can be ignored at the user's discretion, with no detrimental effect on the ability to

continue using the pump normally. The screen display of battery life supports this though it has not been formally tested by BIME.

Patient side occlusion

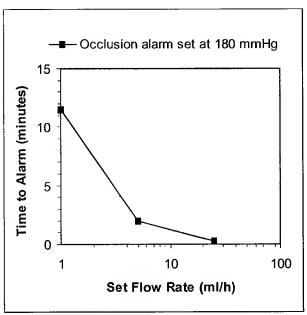
Table 14. Patient side occlusion results for B. Braun Perfusor Space

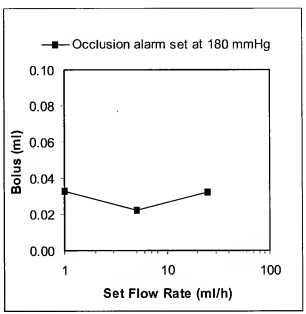
Average time to alarm at 1 ml/h	Average post-occlusion bolus at 1 ml/h
11 minutes 27 seconds	0.03 ml

The pump was tested to establish the speed of response to occlusion and the volume of bolus on release of occlusion. The occlusion alarm pressure is configurable to nine levels between 75 and 900 mmHg. All testing was conducted with 50 ml B. Braun Omnifix syringes. It did not prove possible to reliably run the pump without triggering false occlusion alarms when using the lowest setting (75 mmHg) so level two was used for all tests - a nominal occlusion alarm threshold of 180 mmHg. Being unable to run with some syringes at the lowest alarm pressure is a common finding for syringe pumps that lack in-line pressure inserts, and it leads to longer alarm times than the manufacturer's claim. B. Braun state that their own measurements were made at 75 mmHg. Differences in stiction between batches of syringe may explain the discrepancy. Table 14 shows the average time to alarm and post occlusion bolus at 1 ml/h. Eleven minutes is a relatively long alarm time at 1 ml/h, though response time was consistent and boluses were small, and importantly no negative boluses were recorded in testing. Figures 18 and 19 show the measured time to alarm and post-occlusion bolus at 1, 5 and 25 ml/h.

Figure 18. Time to alarm on occlusion **Figure 19. Bolus released after occlusion**

BIME note: Initial occlusion tests showed very long alarm times (more than one hour at 1 ml/h) if prime was used prior to infusion. This was due to a software bug which failed to reset the occlusion pressure downwards to the user's requested level,





having temporarily raised it to facilitate priming. B. Braun have amended the software and validated the changes to overcome this problem and pumps in clinical use will be upgraded when the next software upgrade is released.

Syringe fit testing

Internal sensors within modern syringe pumps are used to recognise the dimensions of the syringe in use, allowing syringe volume and to some extent syringe brand to be identified, to reduce the possibility of flow rate errors. There are currently no syringe pumps which can recognise all syringe brands correctly, and this test assesses the greatest delivery error that is possible as a result of incorrect syringe recognition - that is, where a user incorrectly registers the size or brand of syringe and the pump does not detect this error.

In the case of the B. Braun Perfusor Space pump, the greatest potential delivery error identified would occur if a user incorrectly loads a 30 ml BD plastipak syringe with the ears horizontal rather than vertical, and then confirms the size suggested by the pump (50 ml BD Plastipak syringe). It is highly unusual to be able to confirm such a large discrepancy; the confirmation in this case is only possible if the ears of the syringe are loaded horizontally rather than vertically. Most syringe pumps measure barrel diameter, so are not prone to this mis-registration. The B. Braun infers barrel diameter from a remote measurement of the ear width.

A two hour test at 5 ml/h was conducted with this set up, and a flow delivery error of -30 % was measured.

Users should always carefully check that the syringe is loaded correctly, and that the correct brand and size of syringe is confirmed on the pump (see manufacturer's comments p. 80).

Special features

Take over mode

This feature is not currently available on the Perfusor Space, but is being implemented by B. Braun on later models with proposed launch date at the end of 2006. It has not been evaluated by BIME.

Continuity of fluid delivery is important for safe infusion therapy, and this can be significantly compromised by the need for syringe changes. Take over mode is designed to overcome this problem, and if effective will provide a significant improvement to drug therapy continuity. There is often a protracted period of non delivery when a syringe is changed, and this is extended by the time it takes for fluid delivery to become established with the new syringe (startup time is around 2 minutes for the Perfusor Space at 1 ml/h, longer at lower flow rates). 'Take over mode' allows two pumps to communicate with one another to coordinate a smoothly timed transition of infusion from one pump to the other, with the intention of

maintaining steady delivery to the patient. There is no evidence to date of the effectiveness of this feature; if effective, it will be a welcome development.

Connectivity

B. Braun through the Space Com offer Ethernet, RS232, USB and wireless connectivity to a wireless local area network (LAN) meaning that infusion pumps can stay in communication with the LAN during patient transfers. B. Braun also have drivers to communicate with a large number of hospital information systems from a variety of manufacturers. The connectivity features of the the Space systems have not been assessed as part of this evaluation, but are extensive and provide a better range of connectivity than is common for infusion devices.

Security features

Some infusion pumps offer security features to prevent unauthorised access and thereby reduce the possibility of inappropriate drug deliveries. The Perfusor Space offers a multi-level security feature, "data lock", activated through the Options menu. It can be set at Level 1, Level 2, or OFF.

At each level certain features can only be accessed by inputting a 4 digit security code. This same code is required when initially activating the data lock. The code will allow a function to be performed, but does not turn off the data lock - this can only be done through the Options menu.

Level one prevents modification of infusion parameters (including rate and VTBI), but allows interruption, start, menu navigation (for status checking) and syringe changes to be performed.

Level two offers higher security and, in addition to the restrictions of level one, syringe change and power off also require the security code.

The function of these security settings have been checked at BIME. They may be found to be appropriate means of restricting access to authorised users in clinical settings where this is indicated.

Additional security features present on the pump include a key operated lock hidden on the base of the pump which can prevent the syringe holder from being opened (allowing removal of syringe and drug only by the key holder).

A 'piston brake' is present to prevent the possibility of free flow during the syringe loading process - it engages temporarily against the plunger until the drive head is fully engaged. This is a unique feature of the B. Braun Perfusor Space and may present a real safety advantage.

Training materials

The training material for the B. Braun Perfusor and Infusomat Space was submitted for evaluation and the findings are summarised here.

The training pack comprises an A4 sized folder containing trainer's and trainee's workbooks and a simulator CD entitled the "Space Training Centre". The trainee's workbook covers a 30 minute familiarisation session to be followed by practice with the pump covering seven clinical scenarios and additional sections focussing specifically on alarms and troubleshooting. Each section concludes with a table for the trainer and trainee to sign and date. The workbook concludes with an opportunity for the trainee to reflect on his/her training, and finally with an assessment completion checklist.

The trainer's workbook contains advice and additional information to ensure that all the trainee's tasks are appropriately observed and the correct execution is achieved.

The Space training centre CD provides a step by step familiarisation with the device, including images of the pump, videos of correct usage, and interactive simulations. The CD can be used on its own - no pump is necessary as the practical exercises are completed using an on-screen interactive simulation (mouse clicks are used to press the pump input keys). The user selects at the start of a session which device (Perfusor, Infusomat or Space Station) to consider. A menu then guides the user through device features in a logical order. Practical exercises are included and these must be completed correctly in a maximum of three attempts per exercise.

On initial use of the CD, the user personalises the training package with their name and clinical position. The user checks boxes to confirm s/he has understood each section of training and, in combination with successfully completed exercises, the package automatically builds a checklist to show the user has gained competency in use of the pump.

A Space system simulation is also provided on the training CD. This software enables the user to operate pumps on a computer screen. An empty Space Station is initially displayed on screen and Infusomat and Perfusor pumps can be placed into the Station and then programmed using mouse clicks instead of finger presses on the pump controls. The displays and visual and audible alerts are all essentially identical to those provided on the real pumps.

This simulator provides a safe and convenient environment for users to work on the pumps and gain familiarity either with basic features or with more advanced programming options such as the drug library facilities.

The training packs and the CD training system are attractive, well written, clearly laid out, relevant, and engaging. They represent a model example of appropriate training aids to ensure competent use of the pump. The extent to which this training reaches end users in an appropriate manner before clinical pump use has not been assessed in this evaluation.

User assessment

Survey of clinical users

B. Braun was asked to provide a list of centres currently using the pump. Questionnaires were then sent to users who offered to provide opinions on their experiences with the pump. Five responses were received.

The questionnaire is reproduced in the appendix of this report.

Users' responses were collated and the results are presented here. Figure 20 is a graphical representation of responses to the multiple choice questions. Clinicians were also invited to make further comments on the pump and these are transcribed below.

Questionnaire survey results:

Training
- cannot fault the training and ongoing support we have received from the company

Instructions
- clear, easy to follow, have kept the info for future reference and continue to refer to it
- covered only what was required, concise
- took a couple of sessions to get used to the instructions

Ease of handling
- on one occasion dropped it as they are smaller than I'm used to

Robustness
- have witnessed the side arms on the Space station (where tubing is stored) break off easily
- syringe drive head prone to being knocked

Pole clamp
- initially kept having to be shown how to disconnect pump from clamp

Syringe loading
- a little fiddly especially if patient is unstable and they need drugs/infusions quickly
- occasional problems with needing to re-load - probably user error

The ease of setting syringe brand and size
- clear and concise

Control panel navigation
- I feel the "C" button should be called "Menu"

Alarms

- good having the facility to increase or decrease alarm tone

Battery charging

- I like the fact that there is the facility to check battery life

List any features you would like to see which are not present on this pump:

- "menu" button to replace "C" button
- Name of drug running through pump

BIME Note: It is possible to set the pump to display the drug name during delivery (and set drug-specific dosing limits) if the drug Library is activated in the configuration.

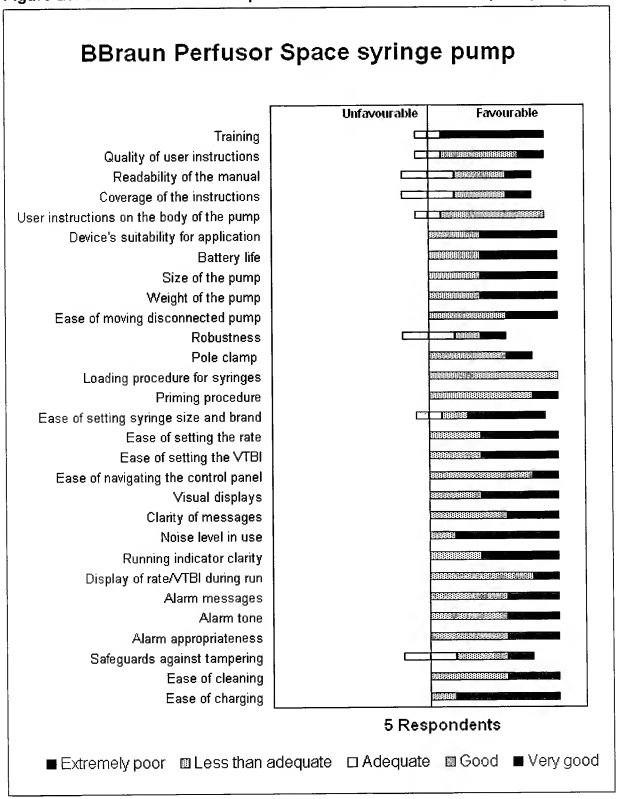
List any features that are present but which are unsuitable for your application:

- none

Are there any additional comments that you would like to make on your experience with the pump?

- The service/repair of the pump is engineer friendly and with a 2 year service interval is ideal for a busy department. B. Braun have provided us with very good after service so far and are quick to rectify any faulty pumps
- If a patient is very unstable and needs "resuscitating" you cannot use the pump quickly. I appreciate though that this does safeguard any errors being made.
- We have only three pumps and although all staff have been trained - as with all new equipment, staff prefer to use pumps they know well, so they have avoided using these pumps in favour of old well used ones! However I have no doubt that if all our pumps were these, staff would swiftly come to use them easily and eventually prefer them to the old ones!, i.e. old habits die hard
- These pumps are excellent for transferring critically ill patients as they have a long and easy to check battery life. They are also easy stackable and light to carry. They are actually very easy to use and work immediately – in other words very little lag time between starting and patients receiving drug

Figure 20. Distribution of user opinions on B. Braun Perfusor Space pump



Heuristic evaluation

The laboratory based assessment of usability of the B. Braun Perfusor Space syringe pump was conducted using a task list comprising common required procedures for this type of pump. The task list was constructed by a combination of interview with appropriate users, and by inspection of the history logs of recently clinically used pumps of this type. The latter step is an innovation to the testing procedure, and provides significant insight into users' achievements with and to some extent, expectations of the pumps. These logs can provide further information on user error and may be exploited further in forthcoming evaluations. The task list was then worked through in the usual manner, according to the protocol, by three trained evaluators. The task list included typical tasks, as well as dealing with common events including an occlusion alarm. Evaluators were also instructed to make a free investigation of functions provided by the pump. Usability problems were noted as the tasks were completed, and these were then editorially combined into a full list of non-overlapping problems. Each usability problem in this final list was then rated for severity by the three evaluators and also scored against a list of 'heuristics' (rules) for good usability.

Previous evaluations have used a system of assessment against 15 possible categories of heuristic violations. Recently published work demonstrates that this system was difficult to apply consistently, and hampered by lack of agreement about the meaning of each category title [4]. As the intention of this heuristic evaluation is eventually to produce a system whereby pumps can be compared for usability, using a few simple scores, this was seen as a weakness of the system. The list of heuristic violations was therefore revised, and redefined (see Appendix for new list versus old list). The scores given below are against the new list, therefore, and should not be compared with previous findings on other pumps.

Table 15 shows the total number of usability problems identified and the number of heuristic violations. The spread of problems in terms of severity is shown in Table 16, determined by mean severity rating from the three evaluators. None of the problems was rated 'catastrophic' (average severity rating > 3.5), those rated as 'major' (average severity rating > 2.5) are described in more detail in Table 17.

Table 15 Total number of usability problems and heuristic violations identified

System	Number of problems	Number of heuristic violations
B. Braun Perfusor Space	43	78

Table 16. Summary of severity ratings for the usability problems identified

System	Cosmetic problems	Minor problems	Major problems	Catastrophic problems
B. Braun Perfusor Space	15	20	8	0

Table 17. Problems identified for the B. Braun Perfusor Space system

Usability problem	Severity
When loading a syringe it is easy not to twist the barrel holder far enough and therefore not open the green ear clamp (see manufacturer's comments)	3.0
It is fiddly to fit a 50ml syringe in the correct position in the pump - the ears only just fit into the space provided in the arrangement, and ears should not be fitted behind green gripper as first guessed.	3.0
With an empty syringe in the pump, opening the "syringe holder" is only partially possible due to proximity of the drive head. However, there is no other obvious way for the user to indicate to the pump that they require a change of syringe.	3.0
The end of syringe alarm for the BD50 is not an "end of travel" alarm, but an overpressure alarm. Backoff therefore occurs and it is possible to restart in a situation where this should not be an option. There is also the possibility that blood could be drawn back into the cannula.	3.0
The pumps (Space Infusomat and Perfusor) are too similar in appearance, possibly leading to wrong type of pump being brought to the bed space	2.7
The main screen is a generally good source of help and it would be nice to see this when loading a syringe, but I can't because the door is open. There is a pretty good diagram on the inside of the door and this is in clear view, but I didn't notice it.	2.7
No message on pump to ensure patient disconnected during prime.	2.7
Pump does not recognise syringe is "inserted" until the syringe holder clamp is closed. Prior message says "Please insert syringe"; should say something like "please insert syringe and close syringe holder". Otherwise pump won't progress, and siphoning remains possible (see manufacturer's comments).	2.7

Some of the difficulties arise because of lack of standardisation across the industry and are not, therefore, specifically criticism of B. Braun but of the general failure to improve safety through use of standard interfaces and terminology. Examples of features which would benefit from general, accepted standards being set, and which were found confusing on this particular pump are:

- Key labels and icons (see below for examples). Also the ON/OFF key does use a standard symbol, but there is little general implementation of this standard, with the result that it is badly understood.
- Text messages in alarm situations
- Physical layout of the pump

The pump has the user interface on the door, which caused several of the observed problems, although these would probably diminish with familiarity. The novice user, however, may be left unable to proceed due to the door being open and messages therefore obscured.

These issues will be explored with reference to a few of the more notable findings.

Messages and icons

Communications from the pump to the user are generally very good, but in a few instances were difficult to interpret. Ambiguities over the meaning of terms arises, leading to possible confusion e.g. 'syringe holder' could represent either of two clamps; 'volume infused' includes all volume delivered since this parameter was last cleared, but could be misinterpreted to mean volume delivered with the current syringe and the relationship between 'Total' and other recorded parameters is confusing.

The labels of keys are not immediately obviously connected to their function in some cases; for instance the C key steps back or cancels things and the ◀ key is used to confirm parameters. The symbol on the "open door" button can also be mistaken for OFF.

Braun have designed much of the functionality of the user interface on these pumps around CD players, on the grounds that users will be universally familiar with the symbols. This is a laudable incentive towards implementing standards, but some of the symbols feel unfamiliar in the context of a medical device. It remains to be seen whether this policy of drawing on standards from other fields will reduce or increase user confusion.

In general, confusion can arise where keys have dual function, for instance a key which operates both START and STOP functions can leave the user unclear whether the pump is running or stopped. On the B. Braun Space system, the dual function START/STOP key was not judged by evaluators to be detrimental or confusing, as other indicators reliably showed whether the pump was running.

Messages provided on the door are unavailable when the door is open; unlike the Space volumetric pump, it is possible to open the door manually, either with or without power being on. This can leave the user without guidance during attempts to load or remove a syringe. If the power is off, then is not possible to either load or remove a syringe - this is unusual for a syringe pump and may further contribute to user confusion. Resultant errors are not foreseeably of serious consequence to the patient, however attempts to forcibly remove or load the syringe may damage the pump.

Alarms

Alarm messages were generally found to be clear, and the urgency of the tone appropriate. A few exceptions were noted. There is no alarm on disconnection of the mains; and the flashing low battery alarm during set up can be confusing. None of

these problems was considered severe enough to be rated greater than 2.7, or appear in the list above.

Some alarm messages were also considered ambiguous, although generally presented in clear english (see positive features below). An example of this was the message: "value not accepted" whilst setting the rate. It was not clear whether the value was OK, but not confirmed, or that the value was outside the settable range. The user can therefore be left unclear on what action to take to remedy.

In addition the end of syringe alarm for the BD50 syringe is activated not by position of the plunger in the syringe, but by over pressure due to the plunger meeting the end of the syringe. This provides an effective alarm, but also activates the backoff, with the result that fluid could be drawn back into the syringe, possibly leading to cannula occlusion.

Physical layout of the pump

Loading the syringe was found to present problems; the ear of the syringe should locate behind a green retaining flange. This was particularly fiddly to achieve, and indeed impossible if the mechanism was not completely rotated by the user, resulting in error messages and the inability to proceed. Removing the syringe could also be tricky, as the drive head of the pump interferes with the 'syringe holder' when at the furthest extent of its travel, as is likely for an empty syringe. For this and other reasons, syringe changeover time was found to be lengthy compared with some manual systems. (The Braun system is partially automated).

The mechanism for releasing a pump from its pole mounting handle was found to be non-obvious to use. This is a prototype design implemented by Braun to reduce the possibility of accidentally releasing pumps. The usability of this mechanism may change in the final production version.

The mechanism for securing the pump in the Space Station could get stuck in a closed position. This has been remedied by Braun in current models, so should not continue to cause problems.

Positive points

Numerous positive aspects of system usability were identified during the evaluation and, while these do not form a part of the heuristic evaluation, they are listed here for information:

- Simple to set up a bolus and to stop it during delivery
- Display clearly shows much of the key information (VTBI, current rate, whether the pump is operating, total infused)
- Good use of colour - green means pump is being used, amber means an alarm, red is a more severe alarm

- Simple to set up and start infusion once syringe loaded
- Priming is easy to control
- The alarm language is very clear and useful, and alarm tones have appropriate levels of urgency e.g. for near end of infusion, and end of infusion
- The battery symbol adequately indicates the level of fill of the battery, and probably also adequately indicates the pump is running on battery
- Post-decimal point figure is smaller for rate 100.4 thereby improving comprehension
- Auto-opening is good - arm of pump draws back on "ON"
- Pole clamp's mechanism of fixing to furniture is good - can be used in vertical and horizontal directions and is easy to handle
- The periodic discharge/recharge of battery (battery maintenance) is a good technical feature and does not adversely affect usability of the pump
- The subtle backlighting of the keypad is good and would be very helpful in low lighting conditions
- The common programming/display of the Space Perfusor and Infusomat is good as it would make pump use easier for staff who use both the volumetric and syringe pumps. The programming steps and display information are practically identical
- When turning power off there is a good delay and appropriate screen messages counting down to power off
- At switch on a battery empty warning was given even though the pump was plugged into mains power. (Although see above for confusion caused by this alarm)
- The instruction manual is small, thorough and well structured and features clear instructions, photographs, diagrams and screen shots
- The pump mounts readily onto a pole clamp or to other pumps (stacking)
- Screen transition from one display to another is distinctive. It is clear that the display has changed
- Macro mode (bigger numbers displayed on screen) may well be useful to some
- On rectifiying an occlusion, the pump presents alarm cancelled message after directing the user to press OK. A soothing tone precedes display of critical parameters, all clearly including units - an excellent recovery from an alarm situation
- VTBI near end alert is clear with text and mutable audible warning
- At the end of a VTBI, it is clear that VTBI is complete and KVO is running, and the KVO flow rate is shown (3 ml/h)
- Good use of display space (clear and uncluttered)
- Running indicator is effective (animated arrows); in addition the direction of travel of the arrows matches the direction of flow of the fluid
- Good that keys autoscroll rate on a prolonged press and this scrolling speeds up after a while
- Good intuitive use of the arrow keys when setting rate and a clear display and good accompanying helpful text on how to change values and when upper limit is reached

- Excellent plain English text messages on screen for information and alerts and alarms, marred by the fact they are not visible with door open
- The instructions on the top of the pump are clearly displayed and easy to read.
- Clear buttons in simple layout
- Rubber feet when on desk prevent the pump from sliding when keys are pressed
- Small and light and easy to handle
- Message and delay on switch off is good
- Countdown clock to end time is very useful
- On incomplete titration, the changed value is not deleted from screen. New value can be cleared or accepted leaving the user clear whether the rate has been changed and indicating any attempts at tampering

Summary of usability assessment

The B. Braun Perfusor Space syringe pump is a pump with many features and generally clear messages and alarms. Increased versatility would normally result in a larger number of usability problems than a simpler pump. The Space syringe pump scored less well than the Space volumetric pump in this usability assessment, but still performed well.

The interface is unfamiliar in format and layout however, and may take users some time to become familiar with. The most significant problem identified in respect of this is the removal from view of the interface, and guiding messages, whilst the user completes loading procedures. This is an inevitable consequence of having the display on the door. Loading the syringe was also problematic due to the physical layout of the mechanism; and the unfamiliar auto-loading procedures.

As with any unfamiliar pump, there is an increased risk of user error during periods of familiarisation, where old procedures are forgotten and replaced by new ones. Purchasers should take steps to ensure all users are adequately trained before using this new infusion system on patients.

Manufacturer's data

Product data

Manufacturer	B. Braun Melsungen AG Postfach 11 20 D34209 Melsungen Germany Tel: 0049 5661 71 4710 Fax: 0049 5661 71 4567 www.bbraun.com info@bbraun.com
Supplier	B. Braun Medical Limited Thorncliffe Park, Sheffield, S35 2PW Tel: 0114 225 9000 Fax:0114 225 9111 www.bbraun.co.uk, info@bbraun.co.uk
CE marking on product?	Yes
Notified body	0123 TÜV
Manufactured to Standard	IEC/EN 60601-1 and IEC/EN 60601-2-24
Country of origin/manufacture	Germany
Price (ex VAT)	£2,200
Size (H x W x D)	68 mm (H) x 249 mm (W) x 152 mm (D)
Weight	Approximately 1.4 kg
Power Supply	100 - 240V
Battery operation	Rechargeable NiMH battery pack, quick and easy exchange without opening device
• battery capacity	Approximately 8 hours at 25 ml/h with 50 ml syringe
• battery charging facilities	Internal battery charger recharges the battery when the pump is connected to external low voltage, recharging time approx 6 h to 100% capacity (external battery charger optionally available)
Facilities	
• syringes accepted	Suitable for use with a range of syringe sizes/types
• syringe extension sets	8722960 Original Perfusor Tubing 150cm, Price £0.30 8722862 - Original Perfusor Tubing 200cm, Price £0.32 8722935 Original Perfusor Tubing 150cm PVC free, Price£0.38 8723060 Original Perfusor Tubing, Price£0.45
• accessories	Space station to enable multiple pumps to be charged via one mains cable, combi lead for connecting to 12V port, Space control extended function user interface for central programming and additional profiles.
• flow rate range	0.01 - 999.9 ml/h (limits are configurable)
• flow rate increments	0.01 - 99.99 ml/h in increments of 0.01 ml/h, 100.0 - 999.9 ml/h in increments of 0.1 ml/h

Product data (continued)

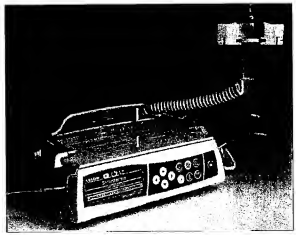
• drug dosing protocols	Library of 720 drugs with programmable drug protocols including hard and soft limits. Drug protocols can be filed into 15 categories for easy access. Take-over mode automatically starts a second pump once the first is finished (end of 2006)
• volume to be infused facility	Yes
• volume infused indicator	Always on-screen in normal display mode
• KVO rate	Configurable to customers requirements
• claimed accuracy	±2% in tests from IEC/EN 60601-2-24
• occlusion pressure	Occlusion alarm pressure 9 levels (75 -900 mmHg in increments of approx. 100 mmHg)
• alarms and alerts	Optical alarm signal with clear text in display and LED. Double-channel audible alarm system for maximum security. Audible alarm for selected drug
• tamperproof	4 digit data lock with 2 levels of lock-out. Level 1 locks out the keypad, level 2 locks the keypad and the disposables
• type of display	Backlit graphic display
• type of infusion fluids	Refer to respective manufacturers' information for possible incompatibilities of equipment with respect to drugs
Nurse call facility	Connection lead staff call systems (max 24V/0.5A/24VA, according to BDE 0834)
Computer interface	B. Braun Space Com utilises Ethernet, RS232, USB and wireless LAN networking. Up to 24 pumps can be stacked in a single tower, with integrated alarms and single power and network cable. Wireless LAN maintains network connection during patient transfer. B. Braun have existing drivers available to connect with all major clinical information systems.
Mounting method	A detachable pole clamp/handle can be fitted to either pump type, three pumps can be connected to one pole clamp. Infusion pumps can be alternatively mounted within Space Station. Both mounting systems are universally compatible with all major pendants and IV poles
Protection against fluid ingress	IP22 (drip protected for horizontal usage)
Electrical safety classification	Class IIb
Model identification	8713030
• Serial number	08824 (pump used for evaluation)
• Software version number	688D

Product Support

Servicing and training	B. Braun Medical Limited Thorncliffe Park Sheffield S35 2PW Tel: 0114 225 9114 Fax:0114 225 9136 www.bbraun.co.uk Technical Support: Tel: 0114 2259204 technicalsupportims.bbmuk@bbraun.com
Provisions for staff training	
• initial in-service training	Provided free of charge to all staff and users (including night staff) competency based training with certification. Educational material includes a Space training centre which is an E learning tool enabling the user to complete a training programme prior to installation and use a simulation tool for practice away from the clinical area, these are also provided free of charge.
• follow-up in-service training	Following installation: 3 month training review and then 6 monthly. All training is free of charge as required.
• first line maintenance training	As part of the on-site installation and commissioning process, structured equipment training will be provided for Medical Technical Officers by a B.Braun Engineer covering clinical application, equipment operation, equipment specification and inspection and first -line fault finding.
• full service/maintenance training	Second line training can be performed on-site for up to 8 Technicians per course, £350 per 2 day course, no limitation to the number of courses held per hospital, all training courses are certified.
Warranty	Two year manufacturer's warranty; supplied as standard. 5 year extended warranty available at time of purchase covering all repairs service and accidental damage ensuring no maintenance costs for the first five years of the product's life - list price £780, volume discounts available.
Maintenance provisions	
• recommended service interval	Manufacturer's recommendation 2 yearly service
• contract service/maintenance	B. Braun offer a range of service contract options for PPM, Repair and Accidental damage. Please contact B. Braun Technical Services for further information
• temporary loan of equipment	Available at supplier's discretion.
Spare parts	
• spares availability	3 day standard delivery. Next day delivery available free of charge on request.
• cost of parts and materials	Prices available on request.
Accompanying manuals	
• user manual	Free of charge with purchase of pump.
• technical/service manual	Free of charge on pump purchase.

B. Braun Infusomat summary

Brief description



The B. Braun Infusomat Space volumetric pump offers extensive features to meet the needs of both general ward use and critical care applications. It is designed to be used on its own or in combination with its sister pump, the B. Braun Perfusor Space. Both pumps can be fitted interchangeably in the B. Braun Space Station to facilitate control and monitoring of multiple infusions, whilst also providing power to multiple pumps using a single cable. The Space Station also features advanced networking facilities (including drivers to link to hospital information systems, and the ability to connect to a wireless LAN) and an enhanced alerting system using large warning lights. Multi level security settings and dose limiting software reduce the likelihood of tampering and use error.

As with any new device, the pumps will appear unfamiliar to new users but the overall Space concept has clearly been developed with a user centred approach and the clear messages and logical programming steps promote safe use.

Advantages

- Small
- Lightweight
- Anti free-flow clamp in the administration set
- Good modular system offered in conjunction with Perfusor Space syringe pump
- User friendly design
- Clear instructions and excellent on-screen messages
- Good battery life and power management
- Easy battery exchange and battery chargeable outside pump
- Good security features
- Bar coding will be offered
- Dose limiting software is offered
- Service/repair is engineer friendly with good after-sales service

Disadvantages

- Some users find motorised set loading procedure fiddly and slow
- No message on the pump to ensure patient disconnected during prime
- When the pump door is opened, the main display cannot be seen
- Similarity of appearance between Infusomat and Perfusor pumps could lead to confusion and the wrong pump being delivered to the bedside from stores

- Small negative boluses (suck back) after occlusion alarm
- Relatively poor long term accuracy at very low flow rates

Faults during testing

On one occasion during testing there was a device alarm with a reported error code 2132 (listed in the technical manual as "internal error"). The user was instructed to switch off and restart the pump. On turning the pump back on, the self test was successful and the pump operated normally. There was no recurrence of this fault.

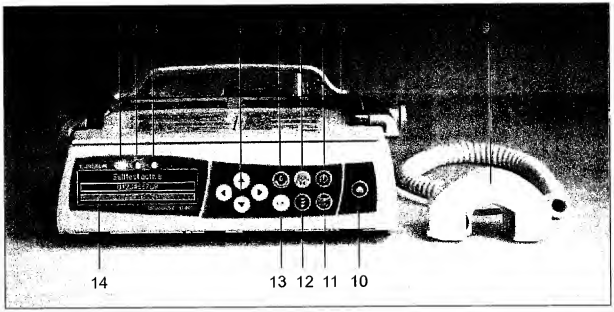
A guide hook on the Space station for retaining the infusion line broke, and required replacement.

Main features

Feature	Detail
Power supply	via B. Braun SpaceStation or mains adaptor (100 ... 240 V AC, 50/60 Hz); 11- 16 V DC via external 12 V supply or via SpaceStation; NiMH rechargeable battery
Administration set	Standard 250 cm Infusomat Space Line used for testing, several alternative lines available including 300 cm line, line with blood filter, UV protected opaque line, siliconized spike, injection port and PVC-free for cytotoxic agents. All share common silicon pumping segment.
Flow rate range	0.1 to 1200 ml/h
Pump mechanism	Peristaltic
Occlusion detection	Nine levels from 0.3 to 1.2 bar (225 to 900 mmHg)
Air detection	Configurable for single bubbles 0.02 to 0.3 ml, cumulative 0.5 to 3.8 ml in one hour (counting air bubbles sized 0.01 ml and larger).
Alarms and alerts	Comprehensive
Price (ex VAT)	£ 2500
Manufacturer	B|Braun Melsungen AG
CE Marking	Yes
Notified body	0123 TÜV
Certified to standard	IEC 60601-1-2; IEC 60601-2-24; EN 55011; BS EN1789:1999

Photographs

Figure 21. B. Braun Infusomat Space volumetric infusion pump



Key

1. Yellow LED: pre-alarm/reminder
2. Green/red LED: Infusing/alarm
3. Blue LED: SpaceControl connection
4. Arrow control keys
5. Cancel / zero / step back key
6. Bolus key
7. ON / OFF key
8. Pole clamp + carry handle
9. Drop sensor (optional)
10. Open door key
11. Start / stop key
12. SpaceControl key
13. OK / confirm key
14. Back lit graphic display
15. Pressure sensor
16. Air sensor
17. Upstream occlusion sensor
18. Pumping section
19. Anti free-flow clamps
20. Release lever

21 SpaceStation with cover and carry handle

22. Status / alarm display
23. Guide hook for infusion lines
24. Knob to unlock pumps

Figure 22. Pump with door open

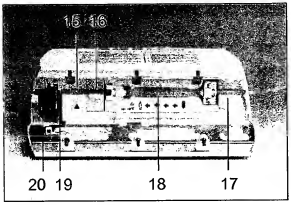
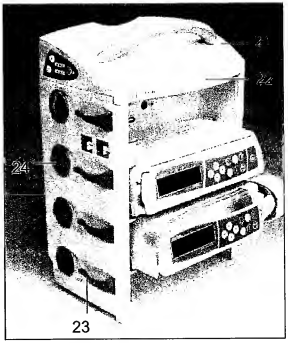


Figure 23. SpaceStation +pumps



Long term accuracy

Table 18. Long term accuracy results for the B. Braun Infusomat Space

Flow rates tested	Greatest over delivery	Greatest under delivery	Accuracy at minimum flow rate
0.1 to 1200 ml/h	+ 0.1 % (at 1 ml/h)	- 6.6 % (at 1 ml/h)	-25.2 % (at 0.1 ml/h)

The Infusomat Space was tested over the full range of available flow rates from 0.1 ml/h to 1200 ml/h. Figures 24 and 25 show flow at 1 ml/h plotted over 2 and 24 hours.

Standard 250 cm Infusomat Space Lines were used for all tests. The alternative sets offered by B. Braun feature the same pumping segment as the standard set so similar fluid delivery performance would be expected.

Excellent delivery accuracy was seen in all tests at flow rates greater than 1 ml/h. A relatively large delivery error was measured at 1 ml/h and an unacceptably large error was seen at 0.1 ml/h. These errors are worse than have been seen on most comparable pumps that have been evaluated. Low flow rates should be avoided when using volumetric pumps since accurate delivery cannot be assumed.

Figures 24 and 25 also demonstrate that at 1 ml/h, periods of negative flow are seen periodically. This discontinuous pattern of flow would be unacceptable for the delivery of fast acting drugs. Efforts to avoid low flow rates should be made for such drugs, and the use of syringe pumps should be considered when low flow rates are clinically indicated since they can offer more consistent fluid delivery, provided the required volume does not involve a syringe change.

Figure 24. Long term accuracy at 1 ml/h over 2 hours

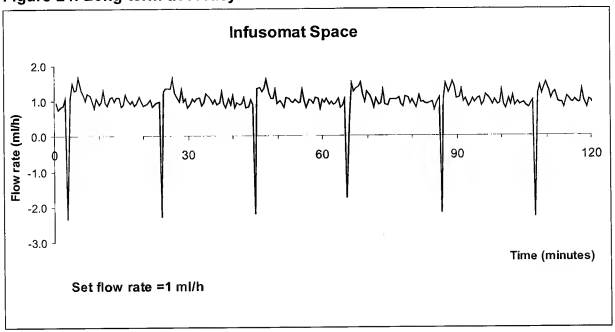
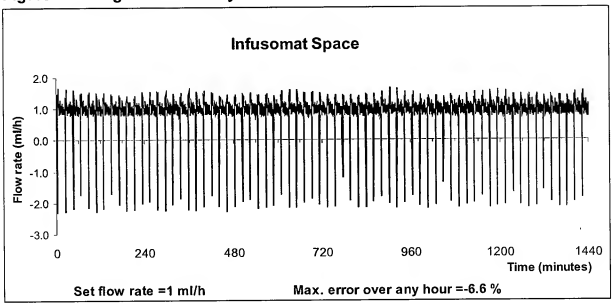


Figure 25. Long term accuracy at 1 ml/h over 24 hours



Short term accuracy and startup time

Table 19. Short term accuracy results for the B. Braun Infusomat Space

Constancy index	Startup time
16 minutes	0.5 minutes

Short term accuracy of infusion pumps is expressed in terms of constancy index. Constancy index can be translated as the shortest half-life of a drug that would be recommended for administration at this flow rate with this pump. Constancy index is measured at 1 ml/h and indicates the minimum period of time over which the flow rate remains within 10% of the mean flow rate.

The constancy index for the Infusomat Space was measured at 16 minutes. As with all volumetric pumps this is long compared with modern syringe pumps. A long constancy index indicates the pump is unsuitable for use with short half life drugs, particularly at low flow rates. Constancy is relatively poor compared with other volumetric pumps, and , as expected is worse than for syringe pumps. This is largely due to the periods of more than 30 seconds during each pumping cycle during which net flow rate is backwards at 1 ml/h i.e fluid is being withdrawn from the patient.

Startup time is a measure of the time taken at the start of an infusion for flow rate to stabilise at the set rate.The startup time for the B. Braun Infusomat Space is 0.5 minutes. This practically instant startup is a typical feature of volumetric pumps.

Volume to be infused

Table 20. Volume to be infused results for the B. Braun Infusomat Space

Target	Actual
1 ml in 60 minutes	0.98 ml (-1.6 % volume error) in 60 minutes
25 ml in 60 minutes	24.96 ml (-0.2 % volume error) in 60 minutes

These results indicate accurate reliable delivery over specified time periods, even when the volume demand is low.

Back pressure

Table 21. Back pressure results for B. Braun Infusomat Space

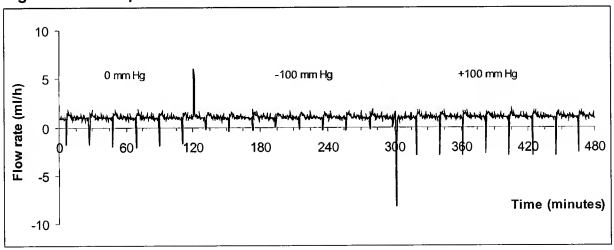
Back pressure	Accuracy	Bolus (when back pressure changes)	Resumption time
0 mmHg	+ 2.3 %	Not applicable	
- 100 mmHg	- 0.1 %	+ 0.04 ml	
+ 100 mmHg	- 1.1 %	- 0.11 ml	3 minutes

The pump was set to deliver at 1 ml/h for eight hours. Initially the pump was aligned level with the cannula outlet. After two hours, the pump was raised by 136 cm to simulate a drop in back pressure of 100 mmHg. After a further three hours, the pump was lowered by 272 cm to increase the back pressure to 100 mmHg above ambient. The pump was not stopped during repositioning.

Figure 26 shows the flow rate of the pump throughout this eight hour test. The disruptions visible on the graph demonstrate the potential hazard to a patient on moving a pump vertically in relation to the venous access site while it is delivering. When the pump is raised, a bolus is delivered to the patient, resulting in a temporary overdose. When the pump is lowered, fluid delivery temporarily ceases due to the backward flow of fluid in the administration set. It should be noted that for this pump these disruptions are small and may be of little significance relative to the erratic nature of fluid delivery.

The time taken to restore normal delivery after a pressure increase (the resumption time) is rapid for this pump.

Figure 26. Back pressure test at 1 ml/h over 8 hours



Container height test

The pump was set to run at 125 ml/h, initially with the bag positioned normally (drip chamber about 30 cm above the pumping mechanism). Flow delivery error was -0.6% over one hour of established flow. The bag was then raised to the maximum extent possible using the standard administration set and flow rate remained acceptable (+0.7 % error). Finally the bag was lowered to be about 50 cm below the pumping mechanism, and again acceptable fluid delivery was maintained by the pump (-3.7% delivery error).

These results show the pump is able to continue delivering accurately when the pump is set up incorrectly with respect to positioning of the fluid container. Users should remain aware however, that such set ups are not recommended in clinical practice.

Flow rate over lifetime of administration set

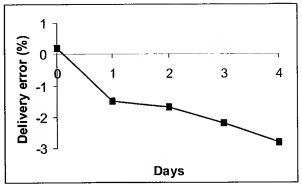
The administration set has a silicon pumping segment and B. Braun state that it will deliver accurately for 96 hours.

The pump was set to deliver at 500 ml/h for 96 hours (4 days) and flow delivery accuracy was measured every 24 hours.

Table 22 and figure 27 show the results of the test. It can be seen that delivery flow rate falls marginally day by day but also that an acceptable level of accuracy is maintained throughout, with an error of only -2.8% at the end of 4 days continuous delivery. This performance is excellent.

Table 22 and Figure 27. Delivery accuracy over the lifetime of the administration set for the B. Braun Infusomat Space

Days into test	Delivery error
0	+ 0.2 %
1	- 1.5 %
2	- 1.7 %
3	- 2.2 %
4	- 2.8 %



Bolus volume accuracy

The pump offers three modes for bolus delivery: manual, volume pre-selection, and rate calculation. In rate calculation mode both pre-selected volume and delivery duration are set and the required flow rate is displayed. Manual and volume pre-selection modes have been tested here. The flow rate for bolus delivery can be configured from 1 to 1200 ml/h, with a default rate of 800 ml/h.

In manual mode, demand volumes of 0.1 ml, 1.0 ml and 3.33 ml (maximum) were used for the tests, and delivery rates of 100, 800 and 1200 ml/h were used for these volumes respectively. The use of high flow rates for small volumes would lead to greater errors than those recorded below. For example, at the default bolus delivery rate of 800 ml/h, a 0.1 ml bolus would be delivered in just 0.45 seconds, and operator accuracy would be likely to greatly affect delivery accuracy.

In volume pre-selection mode the default bolus delivery rate of 800 ml/h was used for all demand volumes.

In each mode, the delivered volume for each bolus demand was measured five times so the average delivery and the worst of five deliveries could be established.

Table 23. Bolus volume accuracy results for the Infusomat Space

Demand volume	Bolus mode	Bolus rate	Average delivery	Greatest single error
0.1 ml	Manual	100 ml/h	0.09 ml	- 20 %
1.0 ml	Manual	800 ml/h	1.03 ml	+ 8.0 %
3.33 ml	Manual	1200 ml/h	3.30 ml	- 0.9 %
0.1 ml	Volume pre-selection	800 ml/h	0.10 ml	+ 10 %
1.0 ml	Volume pre-selection	800 ml/h	0.98 ml	- 2.0 %
5.0 ml	Volume pre-selection	800 ml/h	4.95 ml	- 1.4 %

Table 6 shows the results of bolus volume accuracy testing. Performance is excellent for all demand volumes in volume preselection modes. The measured errors in manual mode are partly dependent on operator skill at demanding the correct bolus volume, and this accounts for the larger errors seen.

It is not always clinically appropriate to use volume preselection mode. Manual mode is often a more immediate way of delivering an urgent bolus. Users should be aware, however, that the volume delivered is less controllable in manual mode, particularly if the required volume is small and the bolus flow rate is high.

The errors are largest for the 0.1 ml bolus in either mode; this is to be expected as the demand is so small.

Battery test

The Infusomat Space has an integrated Nickel Metal Hydride (NiMH) battery with a stated capacity to drive the pump at 100 ml/h for approximately 4 hours. The battery life was tested from fully charged and the pump operated accurately at 125 ml/h for 10 hours 10 minutes. Ten minutes before shutdown, a 'battery near empty' alarm was triggered, which could be muted. The 'battery empty' alarm stopped fluid delivery and advised the user to connect the pump to the mains power supply. On reconnection to mains, the pump is automatically put in standby mode and the previous infusion can be resumed by pressing the start key, with previous rate and volume infused data being preserved. If however the user does not reconnect to mains within 3 minutes of the battery empty alarm, the pump shuts down fully and on subsequent reconnection to mains the previous flow rate and volume infused are not offered on the pump as configured for evaluation.

During normal infusions, the battery level indicator is shown as a symbol on the main display with zero to three bars lit within a battery shaped symbol. There is also a menu option showing the estimated remaining time.

The pump features a 'battery maintenance' facility whereby the pump will automatically prompt the user to periodically carry out a battery discharge/recharge cycle while not in use. This is said to significantly increase the working life of the battery and is therefore a welcome feature. It has been introduced such that it takes a simple key press to carry out when prompted (about once per month) and yet can be ignored at the user's discretion, with no detrimental effect on the ability to continue using the pump normally.

Patient side occlusion

Table 24. Patient side occlusion results for the B. Braun Infusomat Space

Average time to alarm at 1 ml/h	Average post-occlusion bolus at 1 ml/h
8 minutes 10 seconds	-0.02 ml

The pump was tested to establish the speed of response to occlusion and the volume of bolus on release of occlusion. The occlusion alarm level was set to the minimum level (Level 1, 0.3 bar), equivalent to 225 mmHg.

Figures 28 and 29 show the measured time to alarm and post-occlusion bolus at 1, 5 and 25 ml/h. The average time to alarm of 8 minutes 10 seconds at 1 ml/h is long for a volumetric pump. These pumps normally take less time than syringe pumps to alarm. The response time improves, as expected, at higher flow rates and the bolus is either small or negative - the latter implies an overactive backoff system.

Figure 28. Time to alarm on occlusion

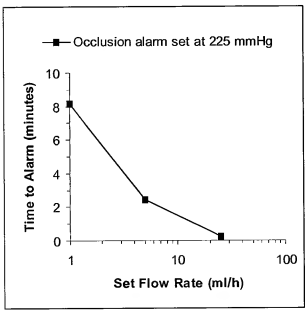
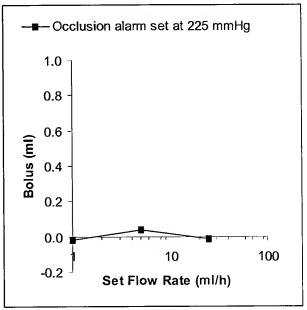


Figure 29. Post occlusion bolus



It should be noted that the response times were highly variable for this pump, with measured alarm times ranging from 1 to 21 minutes at 1 ml/h. This variability was possibly due to priming between tests resetting the occlusion limit; this is a software fault which has now been remedied by B. Braun. The post occlusion bolus was also variable, ranging from -0.08 ml to +0.06 ml at 1 ml/h. There were multiple incidents of small 'negative' boluses, where the bolus reduction system was over active and fluid was drawn back through the cannula. Such instances are undesirable as blood may be drawn into the line increasing the possibility of blockages.

Fluid side occlusion

There is an upstream pressure sensor and an optional drop sensor to detect occlusions between the fluid container and the pump. The upstream sensor is inactive if the drop sensor is connected. The pump was tested both with and without the drop detector connected. The line was occluded soon after commencing delivery at set flow rates of 1 ml/h and 1200 ml/h. The test was repeated five times at each flow rate.

Using the drop sensor, the mean upstream occlusion detection time was between 7 and 33 minutes at 1 ml/h and 3 seconds at 1200 ml/h. It is probable but not proven, that the variability at 1 ml/h was due to the unintended resetting of the occlusion alarm limits by the prime function; this fault has now been remedied by B. Braun. The alarm message comprises an audible alarm, a red flashing LED, and a screen message 'too few drops'.

With the drop detector disconnected, the upstream pressure sensor is automatically activated. In this case, upstream occlusion detection was slightly faster than when using the drop detector. The mean upstream occlusion detection time was 19 minutes at 1 ml/h and 1 second at 1200 ml/h. The alarm message comprises an audible alarm, a red flashing LED, and a screen message 'Check upstream'.

Users should note that the upstream occlusion detection system can only be relied upon to detect wholly occluded lines. With a set flow rate of 125 ml/h, it proved possible to run the pump (with the drop detector attached) for two hours with a partial fluid side occlusion, leading to a significant under infusion (- 50 %) but no alarm being triggered. This has a real possibility of occurring in clinical practice, as the set can be partially occluded in the door, upstream of the pumping segment, unless carefully aligned through the tubing guides during loading.

When testing without the drop detector, it was found that an air bubble usually forms within the pumping section of the administration set when the pump runs at 1 ml/h but is unable to deliver fluid due to an upstream occlusion. Following resolution of the upstream occlusion alarm, this air bubble proceeds down the line and will trigger an air alarm if of appropriate size. This air has possibly been entrained into the slightly gas permeable silicon section of the set under the negative pressure generated by the upstream occlusion, or it may comprise dissolved gasses drawn out of solution by these conditions.

Users should carefully check for the presence of air bubbles in the line following any upstream occlusion.

Air in line testing

The B. Braun Infusomat Space pump features an air detection system to alert the user to either single air bubbles or an accumulation of smaller air bubbles. Both

systems operate simultaneously. The single air bubble alarm system has a default air bubble volume of 0.3 ml and can be configured to detect single bubbles of 0.02 to 0.3 ml volume. The air accumulation system detects bubbles of 0.01 ml or larger and gives an alarm if, in one hour, 1.5 ml of bubbles are detected (default 1.5 ml, configurable from 0.5 to 3.8 ml). The accumulated air is reset to zero whenever the pump is switched off.

BIME testing covers single air bubble detection and the sensitivity was configured to 0.05 ml for the test. When delivering fluid at the test flow rate of 125 ml/h, the pump reliably detected air bubbles of 0.05 ml, giving an auditory and visual alarm and stopping the delivery. Cumulative air detection was not tested.

Special features

Connectivity and Special Features
See B. Braun Perfusor Space p. 36

Training
As for B. Braun Perfusor Space p. 37

User assessment

Survey of clinical users

B. Braun was asked to provide a list of centres currently using the pump. 28 NHS trusts and private clinics were recommended. Questionnaires were then sent to users who offered to provide opinions on their experiences with the pump.

Twenty responses were received, from five NHS trusts. The majority of respondents were nurses, with between two weeks and 10 months of experience with the pump, spanning a range of clinical areas (ITU/High dependency units, haematology, and rheumatology departments). Two responses were received from medical equipment engineers.

Users' responses were collated and the results are presented here. Figure 30 is a graphical representation of responses to the multiple choice questions. Clinicians were also invited to make further comments on the pump and these are transcribed below.

Questionnaire survey results:

Training
- an excellent training package was supplied

Instructions
- clear, concise, I have kept the information for future reference and continue to refer to it
- it took a couple of sessions before I felt confident using the pump
- clear and concise manual

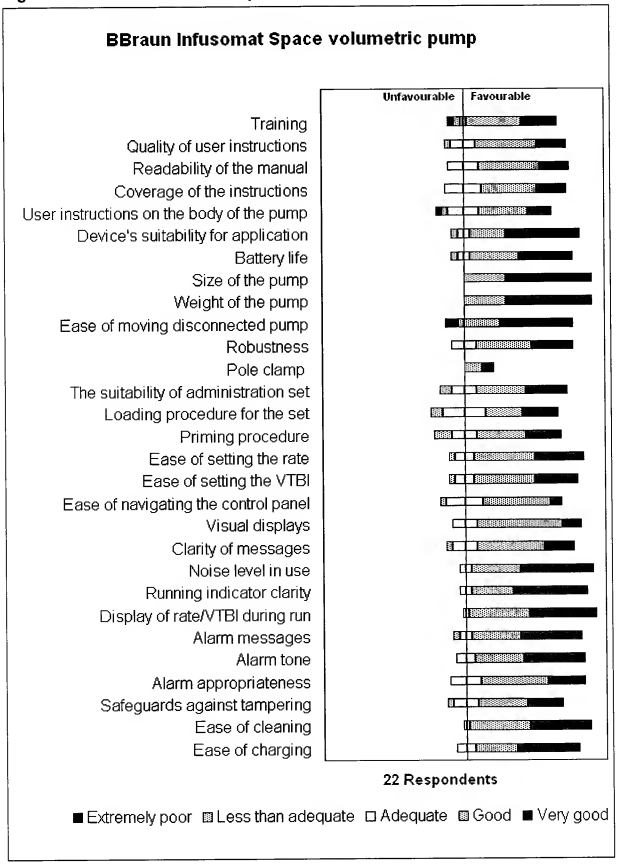
Suitability for purpose
- too many air bubbles
- very good except when giving blood transfusion[+]
- very good; able to deliver a full range of treatments and therapies

[+]BIME Note: entrained air bubbles may have been caused by clinical procedural problems.

Size
- took some time to get used to using a smaller pump
- beneficial having the ability to stack pumps

Weight
- much lighter than previous pumps – easier to move

Figure 30. Distribution of user opinions on B. Braun Infusomat Space pump



Ease of handling

- when in stacking mode, weight extremely heavy
- problems with pump falling out of handle+
- easily disconnects when handling+
- pumps slide off handle+

+BIME NOTE - the handle design has now been modified to address this problem

Robustness

- Space Station side arms that house excess tubing snap off easily
- pump didn't break when dropped
- danger of handle coming off (see BIME note above)

Pole clamp

- needed to be shown a couple of times how to use it

Administration set

- not long enough
- not long enough – no entry port+
- need an injection port+

+BIME NOTE - a longer set and a set with injection port are listed as available from B. Braun

Set loading

- quite fiddly at times
- very fiddly
- feels slow particularly if patient is unstable and they need fluids quickly
- fiddly

Priming the line

- Fiddly, easy to get air bubbles

Setting flow rate

- too fiddly, would be easier with all numbers on pad
- very good, but only when I'd had a lot of practice

Setting VTBI

- too fiddly, would be easier with all numbers on pad

Control panel navigation

- sometimes very long winded when cancelling volume infused
- too time consuming

Alarms

- the five minutes before end of infusion can be a bit previous + annoying
- alarming before the end of infusion annoying, not required
- incomprehensible at times; not in manual
- messages sometimes difficult to understand
- alarm tone irritating

Battery charging

- Attaching the power cable can be fiddly
- good that the battery life can be checked

List any features you would like to see which are not present on this pump:

- easier way of clearing volume infused
- "menu" button to replace "C" button
- Port on administration set to give IV drugs
- Control pad with numbers 0-9
- More secure fixing of handle to prevent falling/dropping*

*BIME NOTE - the handle design has now been modified; a set with an injection port is available as an option

List any features that are present but which are unsuitable for your application:

- longer giving sets which are obtainable
- during blood transfusions the giving set accumulates air bubbles which cause alarm to go off frequently. This can only be resolved either by priming or taking out giving set, but this is time consuming and delays transfusion. The air bubbles accumulate above pump

Are there any additional comments that you would like to make on your experience with the pump?

- air bubbles collect in giving set for no reason and are difficult to get rid of
- very sturdy and user friendly
- opening door just by pushing button would be better instead of having to say "yes" and push another button. Can make setting up infusions time consuming
- better way of clearing volume infused – instead of having to switch off machine
- portability is excellent
- pump cannot be used quickly; this can be frustrating particularly if patient is very unstable
- all staff found this pump user friendly and safe
- preferred older model, easier to load and use
- I do not think that the new pump is as easy to use as the old B. Braun, initially found using the pump quite difficult to understand. It can tell you that there is a problem and I may not understand the problem displayed

- no formal training provided prior to my using these pumps. More sessions were required due to shift work
- no port on giving sets for additional IV infusions
- the plug is too large and heavy to keep moving with pump
- overall a very good IV pump. Problems with "champagne" bubbles in line caused excessive alarms. Once re-calibrated this improved
- very good!
- The service/repair of the pump is engineer friendly and with a 2 year service interval is ideal for a busy department. B. Braun have provided us with a very good after service so far and are quick to rectify any faulty pump

Usability assessment

Heuristic evaluation

The laboratory based assessment of usability of the B. Braun Infusomat Space volumetric pump was conducted using a task list comprising common required procedures for this type of pump. The task list was constructed by a combination of interview with appropriate users, and by inspection of the history logs of recently clinically used pumps of this type. The latter step is an innovation to the testing procedure, and provides significant insight into users' achievements with and to some extent, expectations of the pumps. These logs can provide further information on user error and may be exploited further in forthcoming evaluations. The task list was then worked through in the usual manner, according to the protocol, by three trained evaluators.

The task list included typical tasks, as well as dealing with common events including an air in line alarm and an occlusion alarm. Evaluators were also instructed to make a free investigation of functions provided by the pump. Usability problems were noted as the tasks were completed, and these were then editorially combined into a full list of non-overlapping problems. Each usability problem in this final list was then rated for severity by the three evaluators and also scored against a list of 'heuristics' (rules) for good usability.

Previous evaluations have used a system of assessment against 15 possible categories of heuristic violations. Recently published work demonstrates that this system was difficult to apply consistently, and hampered by lack of agreement about the meaning of each category title [1]. As the intention of this heuristic evaluation is eventually to produce a system whereby pumps can be compared for usability, using a few simple scores, this was seen as a weakness of the system. The list of heuristic violations was therefore revised, and redefined (see Appendix for new list versus old list). The scores given below are against the new list, therefore, and should not be compared with previous findings on other pumps.

Table 25 shows the total number of usability problems identified and the number of heuristic violations. The spread of problems in terms of severity is shown in Table 26, determined by mean severity rating from the three evaluators. No problems were rated 'catastrophic' (average severity rating > 3.5), those rated as 'major' (average severity rating > 2.5), are described in more detail in Table 27

Table 25. Number of usability problems and heuristic violations identified

System	Number of problems	Number of heuristic violations
B. Braun Infusomat Space	52	143

Table 26. Summary of severity ratings for the usability problems identified

System	Cosmetic problems	Minor problems	Major problems	Catastrophic problems
B. Braun Infusomat Space	17	31	4	0

Table 27. Problems identified for the B. Braun Infusomat Space system

Usability problem	Severity
No message on pump to ensure patient disconnected during prime; even when prime is suggested by the pump as a result of air accumulation alarm.	2.7
When the door is opened the main display goes out of sight leaving the user unsure what to do next.	2.7
There was a Device alarm while setting up the occlusion task - error code 2132 (=internal error). User instructed to turn pump off, and subsequently turning pump on the self test was successful and there was no recurrence of this problem. Cause of the error unknown, but system errors requiring the pump to be restarted make pump use more difficult.	2.7
The pumps (Space Infusomat and Perfusor) are too similar in appearance, possibly leading to wrong type of pump being brought to the bed space	2.7

Some of the difficulties arise because of lack of standardisation across the industry and are not, therefore, specifically criticism of B. Braun but of the general failure to improve safety through use of standard interfaces. Examples of features which would benefit from general, accepted standards being set, and which were found confusing on this particular pump are:

- Key labels and icons (see below for examples). Also the ON/OFF key does use a standard symbol, but there is little general implementation of this standard, with the result that it is badly understood.
- Text messages in alarm situations
- Physical layout of the pump

The pump has the user interface on the door, which caused several of the observed problems, although these would probably diminish with familiarity. The novice user, however, may be left unable to proceed due to the door being open and messages therefore obscured.

These issues will be explored with reference to a few of the more notable findings.

Messages and icons

Communications from the pump to the user are sometimes difficult to interpret. All the following features were considered unintuitive by one or more of the evaluators:

- administering boluses using the "OK" key
- the symbolic graph indicating pressure in line
- using the ◄ key to confirm various parameters
- the "open door" symbol (which was sometimes mistaken for an OFF button).

B. Braun have designed much of the functionality of the user interface on these pumps around CD players, on the grounds that users will be universally familiar with the symbols. This is a laudable incentive towards implementing standards, but some of the symbols feel unfamiliar in the context of a medical device. It remains to be seen whether this policy of drawing on standards from other fields will reduce or increase user confusion.

In general, confusion can arise where keys have dual function, for instance a key which operates both START and STOP functions can leave the user unclear whether the pump is running or stopped. On the B. Braun Space system, the dual function START/STOP key was not judged by evaluators to be detrimental or confusing, as other indicators reliably showed whether the pump was running.

Messages provided on the door are unavailable when the door is open; it is also not possible to close or open the door when the pump is off. It is possible to load the set with the pump off, but guiding messages are not available. It is not possible to remove the set when the pump is off as the door cannot be opened.

Alarms

A fault alarm occurred during occlusion testing which required the pump to be restarted. This would cause usability problems due to delay in real clinical situations, if it recurred regularly. Alarm messages were generally found to be clear, and the urgency of the tone appropriate. A few exceptions were noted. There is no alarm on disconnection of the mains; the flashing low battery alarm during set up can be confusing; and there is no alarm if the wrong set is selected from the menu. None of these problems was considered severe enough to be rated greater than 2.7, and do not, therefore, appear in the list on p.68.

Some alarm messages were also considered ambiguous, although generally presented in clear english (see positive features below). An example of this was the message: "value not accepted" whilst setting the rate. It was not clear whether the value was OK, but not confirmed, or that the value was outside the settable range. The user can therefore be left unclear on what action to take to remedy.

Physical layout of the pump

The set loads from right to left which is conventional for continental Europe, but might feel unfamiliar, and lead to errors in UK settings. Familiarity would reduce the likelihood of error here. Unlike some other continental modular units which offer both syringe and volumetric pump, the volumetric and syringe pump flow directions are the same which reduces potential for confusion.

The mechanism for releasing a pump from its pole mounting handle was found to be non-obvious to use. As the version tested was a prototype design implemented by B.Braun to reduce the possibility of accidentally releasing pumps, the usability of this mechanism may improve in the final production version.

The mechanism for securing the pump in the Space Station could get stuck in a closed position. This has been remedied by B. Braun in current models, so should not continue to cause problems.

Minor problems were experienced with misloading the tubing guides at inlet and outlet, although no free flow was achieved.

Alarm lights are not visible from a wide angle, unless the pump is in the Space station.

Positive points

Numerous positive aspects of system usability were identified during the evaluation and, while these do not form a part of the heuristic evaluation, they are listed here for information:

- The periodic discharge/recharge of battery (battery maintenance) is a good technical feature and does not adversely affect usability of the pump
- The subtle backlighting of the keypad is good and would be very helpful in low lighting conditions
- The common programming/display of the Space Perfusor and Infusomat is good as it would make pump use easier for staff who use both the volumetric and syringe pumps. The programming steps and display information are practically identical
- When turning power off there is a good delay and appropriate screen messages counting down to power off
- The pump recognises removal of the drop detector, giving a text message and audible alert - it then functions without the detector
- A docking port on the pump handle/pole mount neatly holds the drop detector when not in use
- Misloads seem unlikely, and when achieved do not result in free flow. An appropriate message 'line not properly inserted' is displayed and the door reopens, compeling the user to make remedy
- The inactivity alert includes a flashing yellow warning triangle inside the pump - i.e. it is visible with the door open
- There is a clearly visible path for the set to follow with good direction arrows and loading diagrams inside the pump when loading, and the design of set with hooks and anti free flow clamp make attempts at loading the set with the flow direction reversed unlikely

- At switch on a battery empty warning was given even though the pump was plugged into mains power. (Although see above for confusion caused by this alarm)
- The instruction manual is small, thorough and well structured and features clear instructions, photographs, diagrams and screen shots
- The pump mounts readily onto a pole clamp or to other pumps (stacking)
- The alarm language is very clear and useful, and alarm tones have appropriate levels of urgency e.g. for near end of infusion, and end of infusion
- The battery symbol adequately indicates the level of fill of the battery, and probably also adequately indicates the pump is running on battery
- Post-decimal point figure is smaller for rate 100.4 thereby improving comprehension
- Screen transition from one display to another is distinctive. It is clear that the display has changed
- Macro mode (bigger numbers displayed on screen) may well be useful to some.
- On rectifiying an occlusion, the pump presents alarm cancelled message after directing the user to press OK. A soothing tone precedes display of critical parameters, all clearly including units - an excellent recovery from an alarm situation
- VTBI near end alert is clear with text and mutable audible warning
- At the end of a VTBI, it is clear that VTBI is complete and KVO is running, and the KVO flow rate is shown (3 ml/h)
- Good use of display space (clear and uncluttered)
- Running indicator is good (animated arrows)
- Good that keys autoscroll rate on a prolonged press and this scrolling speeds up after a while
- Excellent plain English text messages on screen for information and alerts and alarms, marred by the fact they are not visible with door open
- The instructions on the top of the pump are clearly displayed and easy to read
- Clear buttons in simple layout
- Rubber feet when on desk prevent the pump from sliding when keys are pressed
- Small and light and easy to handle
- Unusual and possibly valuable that this volumetric pump offers both manual and pre-set bolusing
- Countdown clock to end time is very useful
- It is possible to run the pump without drop detector, and a suitable warning is provided. The user must set a VTBI under these conditions which is appropriate
- Pump quiet in operation
- On incomplete titration, the changed value is not deleted from screen. New value can be cleared or accepted leaving the user clear whether the rate has been changed and indicating any attempts at tampering

Summary of usability assessment

The B. Braun Infusomat Space volumetric pump is a pump with many features and generally clear messages and alarms. Increased versatility would normally result in a larger number of usability problems than a simpler pump. In view of this, the Space volumetric pump scored particularly well in this usability assessment, as further evidenced by the large number of positive comments made by evaluators.

The interface is unfamiliar in format and layout however, and may take users some time to become familiar with. The most significant problem identified in respect of this is the removal from view of the interface, and guiding messages, whilst the user completes core procedures. This is an inevitable consequence of having the display on the door.

There is an increased risk of user error during periods of familiarisation, where old procedures are forgotten and replaced by new ones. Purchasers should take steps to ensure all users are adequately trained before using the system on patients.

Manufacturer's data

Product data

Manufacturer	B. Braun Melsungen AG Postfach 11 20 D34209 Melsungen Germany Tel: 0049 5661 71 4710 Fax: 0049 5661 71 4567 www.bbraun.com info@bbraun.com
Supplier	B Braun Medical Limited Thorncliffe Park, Sheffield, S35 2PW Tel: 0114 225 9000 Fax:0114 225 9111 www.bbraun.co.uk, info@bbraun.co.uk
CE marking on product?	Yes
Notified body	0123 TÜV
Manufactured to Standard	IEC/EN 60601-1; IEC/EN 60601-2-24; EN1789:1999
Country of origin/manufacture	Germany
Price (ex VAT)	£2,500 8700036SP Standard Set, Price £1.36 8700087SP Injection Port, Price £1.60 8270066SP Blood Set, Price £1.66 8250731SP Neutrapur PVC Free, Price £1.83
Size (H x W x D)	68 mm (H) x 214 mm(W) x 124 mm(D)
Weight	Approximately 1.4 kg
Power Supply	100 - 240 V
Battery operation	Rechargeable NiMH battery pack, quick and easy exchange without opening device
• battery capacity	Approximately 4 hours at 100ml/h
• battery charging facilities	Internal battery charger recharges the battery when the pump is connected to external low voltage, recharging time approx 6 h to 100% (external battery charger optionally available)
Facilities	
• pumping mechanism	Peristaltic
• administration sets	Full range, all sets have inline anti-free-flow clamp
• accessories	Drop sensor; Space station to enable multiple pumps to be charged via one mains cable; combi lead for connecting to 12 V port. Short IV stand attached to the pole clamp; Space control extended function user interface for central programming and additional profiles.
• flow rate range	0.1 - 1200 ml/h
• flow rate increments	0.1- 99.99 ml/h in 0.01 ml/h increments 100.0- 999.9 ml/h in 0.1 ml/h increments 1000 - 1200 ml/h in 1 ml/h increments

Product data (continued)

• drug dosing protocols	Library of 720 drugs with programmable drug protocols including hard and soft limits. Drug protocols can be filed into 15 categories for easy access. Take-over mode automatically starts a second pump once the first is finished (end of 2006).
• volume to be infused facility	Yes
• volume infused indicator	Always on-screen in normal display mode
• KVO rate	Configurable to customers' requirements
• claimed accuracy	± 5% over 96 h with Original-Infusomat® Space Line
• occlusion pressure	Occlusion pressure adjustable in 3 steps from 225 – 1125 mmHg
• alarms and alerts	Optical alarm signal with clear text in display and LED. Double-channel audible alarm system for maximum security. Audible alarm for selected drug
• tamperproof	4 digit data lock with 2 levels of lock-out. Level 1 locks out the keypad, level 2 locks the keypad and the disposables
• type of display	Backlit graphic display
• air in line detection	Internal air sensor. Optional drop sensor
• type of infusion fluids	B. Braun advise: "Refer to respective manufacturer's information for possible incompatibilities of equipment with respect to drugs"
Nurse call facility	Connection lead staff call systems (max 24 V/0.5 A/24 VA, according to BDE 0834)
Computer interface	Space utilises Ethernet, RS232, USB and wireless LAN networking. Up to 24 pumps can be stacked in a single tower, with integrated alarms and single power and network cable. Wireless LAN maintains network connection during patient transfer. B. Braun have existing drivers available to connect with all major clinical information systems.
Mounting method	A detachable pole clamp/handle can be fitted to either pump type, three pumps can be interlinked and connected to one pole clamp. Infusion pumps can be alternatively mounted within space station. Both mounting systems are universally compatible with all major pendants and IV poles
Protection against fluid ingress	IP22 (drip protected for horizontal usage)
Electrical safety classification	Class IIb
Model identification	8713050
• Serial number	03408 used for evaluation
• Software version number	688D

Product Support

Servicing and training	B. Braun Medical Limited Thorncliffe Park Sheffield S35 2PW Tel: 0114 225 9114 Fax:0114 225 9136 www.bbraun.co.uk Technical Support : Tel: 0114 2259204 technicalsupportims.bbmuk@bbraun.com
Provisions for staff training	
• initial in-service training	Provided free of charge (FOC) to all staff and users (including night staff); competency based training with certification. Educational material includes a Space training centre which is an E-learning tool enabling the user to complete a training programme prior to installation and use a simulation tool for practice away from the clinical area, these are also provided FOC
• follow-up in-service training	Following installation 3 month training review and then 6 monthly. All training is free of charge as required.
• first line maintenance training	As part of the on-site installation and commissioning process, structured equipment training will be provided for Medical Technical Officers by a B.Braun Engineer covering clinical application, equipment operation, equipment specification and inspection and first -line fault finding.
• full service/maintenance training	Second line training can be performed on-site for up to 8 Technicians per course, £350 per 2 day course, no limitation to the number of courses held per hospital, all training courses are certified.
Warranty	Two year manufacturer's warranty; supplied as standard. 5 year extended warranty available at time of purchase covering all repairs service and accidental damage ensuring no maintenance costs for the first five years of the product's life - list price £780, volume discounts available.
Maintenance provisions	
• recommended service interval	Manufacturers recommendation two yearly service
• contract service/maintenance	B. Braun offer a range of service contract options for PPM, repair and accidental damage. Please contact B. Braun Technical Services for further information
• temporary loan of equipment	Available at supplier's discretion.
Spare parts	
• spares availability	3 day standard delivery. Next day delivery available Free of charge on request.
• cost of parts and materials	Prices available on request.
Accompanying manuals	
• user manual	Free of charge with purchase of pump.
• technical/service manual	Free of charge on pump purchase.

Appendix

Heuristic review protocol

Three experts (two experts in infusion systems and one expert in usability assessments of electronic devices) independently assessed the pump. A series of tasks was designed in consultation with clinical users of infusion pumps, and by inspecting the history logs of recently clinically used pumps. This task list was then worked through by the experts. During this work-through, usability problems were noted and classified according to violation of standard usability heuristics.

Tasks for heuristic review of usability (volumetric)

Before starting the tasks, read the appropriate sections of the instruction manual. If tasks are unclear, ask for clarification of the meaning of the task (the method of actually carrying out the task will not be discussed, however).

Mount the pump on a pole, prime a set with fluid using the manufacturer's recommended technique.

1. Set up an infusion to run at 100 ml/h with drop detector. Start the infusion and check it is running properly.
2. After the infusion has delivered 2 ml, change the rate to 20 ml/h and, if necessary, restart the pump.
3. Start an infuson at the maximum rate, with VTBI of 50 ml without the drop detector if possible.
4. After the infusion has stopped observe whether KVO rate is operating.
5. Stop the pump and ensure delivery to patient has stopped.
6. An assistant will start an infusion at an unknown rate, and occlude the line at some point. Resolve the occlusion, observe the volume delivered at resumption, and restart at the former rate.
7. Explore the pump and its functionality, covering issues relating to general handling, pole clamping, power supply, button pressing, display clarity and readability, button labelling, air-in-line and other alarms, available infusion options and so on.

(See below for tasks for syringe pump)

On completion of the tasks, each reviewer then allocated one or more category of "heuristic violation" to each usability problem he or she had discovered. The previously used list of 15 heuristics (or "rules of thumb") for good usability has recently been revised for improved usability of the list. The new list was used for the present evaluation.

Heuristics and meaning of a violation

Previous list

1. Consistency - the pump functions in unexpected ways or conventions are defied.
2. Visibility - the current operating status is not made clear to the user.
3. Match - the pump features do not match the tasks or requirements of the user.
4. Minimal - extraneous or low priority information is a dangerous distraction.
5. Memory - user has to remember how to do a task to do it correctly.
6. Feedback - pump fails to give prompt appropriate feedback (e.g. following user action or alarm situation).
7. Flexibility - appropriate shortcuts or defaults are not offered.
8. Message - error messages are not clear, precise, constructive and polite.
9. Error - use errors are possible that could be made impossible.
10. Closure - user is left uncertain whether goal achieved or task completed.
11. Undo - user cannot reverse an action.
12. Language - words used are not understandable to users.
13. Control - user cannot control pump as required OR user action produces surprise outcome.
14. Document - appropriate help is not provided when needed.
15. Physical - shape, size, layout or orientation makes task difficult or unsafe.

Revised list

1 Unexpected/unconventional - the pump functions in unexpected ways or conventions are defied, or user action produces surprise outcome.
2 Operating status unclear - the current operating status is not made clear to the user; to include user being uncertain whether goal achieved or task completed.
3 Useful features missing - the pump features do not match the tasks or requirements of the user, and/or user cannot control pump as required, and/or appropriate shortcuts or defaults are not offered.
4 Distracting info - extraneous or low priority information is a dangerous distraction.
5 Memory challenge - user has to remember how to do a task to do it correctly.
6 Bad message, (feedback, symbol, document, help) - alarms, error messages, documents, symbols, help or info messages are not clear, prompt, appropriate, precise, constructive, in a familiar vocabulary and polite.
7 Use error possible - use errors are possible that could be made impossible, including due to bad physical layout.
8 No undo - user cannot reverse an action.

The original list is based on published research [2]. Minor modifications have been introduced to improve consensus when applying the list, and make it easier to apply to medical devices. All concepts in the revised list are drawn from the original list, however. It continues to be the case that more than one heuristic violation may be allocated to each usability problem identified.

The three evaluators' lists of problems were collated into a "master list" through appropriate checks to remove duplicate problems.

Each reviewer scored each problem from the master list for severity on a five point scale according to the following guidelines (also adopted from the same published method of heuristic review for medical infusion devices) [2].

Severity ratings

Original severity scale
If a heuristic is violated, it is given a severity rating based on the following scales:

0 not a usability problem at all;
1 cosmetic problem only. Need not be fixed unless extra time is available;
2 minor usability problem. Fixing this should be given low priority;
3 major usability problem. Important to fix. Should be given high priority;
4 usability catastrophe. Imperative to fix this before product can be released.

As a guideline for rating the problems, we consider the proportion of users who will experience it, the impact it will have on their experience with the product, and whether the usability problem will be a problem only the first time they encounter it, or whether it will persistently bother them. A persistent problem with a major impact that most users will encounter will get the highest severity rating.

Revised severity scale used for this report
Each evaluator rates each identified problem for severity on the following scale

0 not a usability problem
1 cosmetic problem only.
2 minor usability problem.
3 major usability problem.
4 usability catastrophe.

To rate the problem, evaluators should consider the following factors

Potential impact on patient safety
Impact on clinician's experience
Likelihood of occurrence
Whether the problem will only affect inexperienced users.

Problems that could directly lead to patient harm should be given high severity ratings, particularly if they appear likely to occur in clinical use

Finally the three severity ratings for each usability problem were averaged to give an overall severity assessment for that problem.

The total number of usability problems, the total number of heuristic violations and the spread of severity ratings were assessed.

References

1. Davey C., Dunn T.S., Lipson M.M., Developing a usability testing approach for evaluating medical devices within the NHS., World Congress on Ergonomics, 2006.
2. Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. J.Biomed.Inform. 2003; 36: 23-30

Tasks for heuristic review of usability (syringe)

Before starting the tasks, read the appropriate sections of the instruction manual. If tasks are unclear, ask for clarification of the meaning of the task (the method of actually carrying out the task will not be discussed, however).

Mount the pump on a pole, prime a set with fluid using the manufacturer's recommended technique.

1. Set up an infusion to run at 100.4 ml/h. Start the infusion and check it is running properly.
2. After the infusion has delivered 2.04 ml, change the rate to 20 ml/h and, if necessary, restart the pump.
3. Start an infuson at the maximum rate, with VTBI of 5 ml and volume of 10 ml in the syringe.
4. After the infusion has stopped observe whether KVO rate is operating.
5. Exchange the syringe for a new one, and start it at the same rate with VTBI of 5 ml. Note the time taken to accomplish this procedure.
6. Respond to any alarms
7. Stop the pump and note whether delivery to the patient has stopped.
8. An assistant will start an infusion at an unknown rate, and occlude the line at some point. Resolve the occlusion, observe the volume delivered at resumption, and restart at the former rate.
9. Explore the pump and its functionality, covering issues relating to general handling, pole clamping, power supply, button pressing, display clarity and readability, button labelling, other alarms, available infusion options and so on.

Manufacturer's comments

The following comments on this report were provided by Codan Argus and Codan Ltd, UK

Codan Argus do not agree with this evaluation report. The CODAN ARGUS 708 pump is a Swiss high quality product with an excellent price/performance relationship. The pump can be used for standard applications with the highest degree of accuracy, as well as in specialist cancer therapies, blood transfusions, enteral nutrition and neo-natology.

The configuration is always agreed with the individual hospital before use - but this was not taken into consideration when configuring a pump for the evaluation. (This comment refers to features within the report marked with a star [*].)

The configuration changes can be done very quickly and safely via PC using our user-friendly, windows based ARGUS service software.

The F-52 failure can happen when the pump sits un-used for a long period without charging the battery. After a longer than 3 month period un-used, the battery requires several cycles to re-format the cells and to achieve the full capacity.

Regarding the dual function of the MODE key we can say that this is part of our safe user friendly philosophy. Parts of this philosophy are also represented by the alarm and operation icons which are familiar to the successful syringe pump CODAN ARGUS 600 S.

The following comments on this report were provided on behalf of B. Braun Melsungen AG by Christine McCabe, Marketing Manager, B. Braun Medical Ltd.

We welcome the overall results of this evaluation which reflect the positive market feedback and acceptance of these products in all clinical areas.

In reference to disposable handling and related findings there are clear graphical instructions on both pumps to ensure correct disposable handling. The pump software does not allow the user to proceed after recognising incorrectly loaded disposables.

A potential loading error of the BD 30ml syringe is only possible after performing two independent loading steps incorrectly, i.e. loading the syringe and confirmation of the syringe type (50ml instead of 30ml). We have not received any reports from users about partial upstream occlusion with Infusomat Space.

The syringe end alarm does not always function with the BD 50ml syringe (pressure alarm instead) due to very wide syringe manufacturing tolerances. The pump software has been amended to reflect these syringe tolerances and to ensure the syringe end alarm always functions.

B.Braun have been unable to reproduce the momentary disruptions to smooth delivery with the long term testing of Perfusor Space and will carry out additional tests with the pump used at BIME.

Following the battery flat alarm the pumps can be configured to continue last therapy after power off.